A strategic direction for change:
A review of the regulations under the
food and drugs act.
Vol. 3

Health Canada Santé Canada

A Strategic Direction for Change

A review of the

regulations under the

Food and Drugs Act

Volume 3

Health Protection Branch
April 1995

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A STRATEGIC DIRECTION FOR CHANGE

A REVIEW OF THE REGULATIONS UNDER THE *FOOD AND DRUGS ACT*

VOLUME 3

IMPLEMENTATION PLAN

Our mission is to help the people of Canada maintain and improve their health.
Health Canada

Note: On June 25, 1993, the federal government announced the reorganization of certain departments including Health and Welfare Canada and Consumer and Corporate Affairs Canada. Phase I of the Regulatory Review was conducted before June 25, and consequently, Volumes 1 and 2 reflect the responsibilities and mandates operating prior to that date. Volume 3 also reflects the changes to the Health Protection Branch organization which occurred on April 15, 1994 resulting from the HPB Program Review.

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* Including comments from written submissions and seven cross-country consultation workshops.

ABBREVIATIONS

AAFC	Agriculture and Agri-Food Canada
BFRIIA	Bureau of Food Regulatory, International and Interagency Affairs, Health Canada
CCAC*	Consumer and Corporate Affairs Canada
DFO	Department of Fisheries and Oceans
HC	Health Canada
HPB	Health Protection Branch
IC	Industry Canada
PDP	Principal Display Panel

* This department was disbanded during the Government reorganization of June 25, 1993. CCAC staff, responsibilities and mandates with respect to food were divided between Industry Canada and Agriculture and Agri-Food Canada.

INTRODUCTION

BACKGROUND

In October 1992, the Treasury Board requested that Health Canada review all regulations that were promulgated with respect to the ***Food and Drugs Act***. The review applied mainly to the work of the Health Protection Branch (HPB) and Agriculture and Agri-Food Canada (AAFC), and programs falling under the ***Food and Drugs Act and Regulations***. The findings of the Regulatory Review have been published in a series of volumes entitled ***A Strategic Direction for Change: A Review of the Regulations Under the Food and Drugs Act.***[1]

To accomplish this review, staff of HPB and CCAC and external stakeholders were asked to identify those regulations which may no longer serve their intended purpose. This process was completed by seven review teams which employed both written consultation and a cross-Canada series of meetings with stakeholders. This consultation phase culminated in the development of a number of recommendations contained in ***Volume 1*** that was released on October 29, 1993. The 43 issues papers which formed the basis of the discussions at the stakeholder meetings were subsequently published as ***Volume 2*** in December 1993 and included a compilation of stakeholders' comments. ***Volume 3*** outlines the plan to implement the review teams' recommendations.

FOCUS OF THE REGULATORY REVIEW

The Regulatory Review focused on three areas. The first two address and reaffirm the commitment to the mandate of Health Canada in the areas of health and safety, and of Agriculture and Agri-Food Canada for protection against consumer fraud. The third focus of the Review pertains to the competitiveness of industry. The three key factors which were identified as enhancing competitiveness included simplification, responsiveness and harmonization. Changes to the regulatory system in these areas should allow industry to be more responsive to market demands and be more competitive.

This approach is consistent with the objective of Regulatory Review as reiterated in the ***Federal Regulatory Plan 1994***, that is: "to reduce the regulatory burden on Canadian business and individuals." To accomplish this goal, the President of Treasury Board recognized that workable alternatives to regulation and partnerships with other governments and the private sector would be important elements in achieving more efficient regulation. Both elements will be incorporated as features of the implementation.

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[1] ***Volume 1*** contains the recommendations; ***Volume 2*** contains the compilation of the issues papers and comments; ***Volume 3*** contains the implementation plan. These documents will be referred to simply as **Volume 1, 2** or **3.**

The intent of ***Volume 3*** is to outline the actions Health Canada and Agriculture and Agri-Food Canada intend to undertake, to reaffirm the commitment to open and transparent consultation, to provide for the establishment of communication channels and to indicate consultation mechanisms to be used.

THE RECOMMENDATIONS

Volume 1 contained over 150 recommendations addressing issues as diverse as food safety, food labelling, medical devices, pharmaceutical drugs and cosmetics. Some recommendations pertained to Branch-wide issues which are discussed below under "Branch Level Initiatives" and in Review Team 1 under the heading "Recommendations Related to Larger HPB Initiatives". The recommendations specific to Drugs and Medical Devices are addressed below and will not be addressed further herein.

REVIEW TEAMS 1-5: FOOD

Review Team 1 made recommendations pertaining to both Branch level and food-related issues. Review Teams 2-5 examined food-related regulations exclusively. Together, Teams 1 to 5 made over 130 recommendations regarding food safety and food labelling. Thirty eight of these recommendations were directed to development of policy, while 93 recommendations will require some form of regulatory amendment. The number of recommendations for each government lead agency (HC for food safety issues and AAFC for food labelling issues) and for each division of the ***Food and Drug Regulations*** (Parts A, B, and D) are contained in Appendices I and II respectively. A complete Inventory of the Food Regulations Reviewed During the 1993 Regulatory Review is provided at Appendix III. An Inventory of Recommended Policy Development Initiatives can be found as Appendix IV.

Many of the proposals outlined in this document will require extensive consultation and may result in their final promulgation within two to five years. For information purposes, the ten steps necessary to complete the regulatory amendment process are summarized in Appendix V. The regulatory changes proposed for implementation herein were announced in the ***Federal Regulatory Plan 1995*** as HCan/95-29-O-I Initiatives Resulting from the Departmental Regulatory Review (p. 89). For further information regarding the implementation of the food-related recommendations of the Regulatory Review contact:

Director
Bureau of Food Regulatory, International and Interagency Affairs
Food Directorate
Room 200, HPB Building
Tunney's Pasture
Ottawa, Ontario K1A 0L2
Tel: 613-957-1748
Fax: 613- 941-3537

REVIEW TEAM 6: MEDICAL DEVICES

The Medical Devices Review Committee, chaired by Mr. Ambrose Hearn, President and Chief Executive Officer of the Ottawa Civic Hospital, was appointed in March 1991. Its purpose was to formulate recommendations for the Minister of National Health and Welfare concerning the regulation of medical devices and associated activities. The sale of medical devices is subject to the ***Medical Devices Regulations*** under the ***Food and Drugs Act***. Following the release of the Committee's Report (***Hearn Report***) in August 1992, a Development Plan for an Improved Medical Devices Regulatory Program was prepared. The Medical Devices Review Committee endorsed the development plan at its final meeting on April 14-15, 1993.

One of the primary recommendations of the Committee was to develop a risk-based classification of medical devices and an associated regulatory system, whereby the degree of scrutiny afforded a device is related to the risk. This Risk-Based Classification System is being developed with the assistance of the external Advisory Committee on the Risk-Based Classification Number.

The ***Medical Devices Regulations*** require major changes in order to implement a system based on risk. It is anticipated that the new regulations will be a balance of pre-market evaluation (for highest risk devices), good manufacturing practices (quality systems) and post-market surveillance. Revisions to the regulations should begin after acceptance of the Risk-Based Classification System. The four recommendations of Review Team 6 (Medical Devices) have been incorporated into the Development Plan for an Improved Medical Devices Regulatory Program and therefore, will not be discussed further herein. For more information regarding the implementation of the recommendations of Review Team 6, contact:

Dr. R. Tobin
Director
Medical Devices Bureau
Environmental Health Directorate
Environmental Health Centre
Tunney's Pasture
Ottawa, Ontario K1A 0L2
Tel: 613-952-7125
Fax: 613-957-7318

REVIEW TEAM 7: DRUGS

In January 1992, Dr. Denis Gagnon, the Vice-Rector of Research at the University of Laval, was commissioned by the Minister of Health and Welfare Canada to conduct a review of the drug approval system in Canada and to advise the Minister on the regulatory model and drug approval processes that would best serve the Canadian public into the 21st century. The ***Gagnon Report***, containing 152 recommendations, was released on November 30, 1992.

In order to include recommendations from several other exercises within the Department, including internal audits and evaluations, Regulatory Review, and strategic planning and resource review, and to include all activities of the Drugs Directorate, the scope of the Gagnon implementation exercise was broadened to become a Drugs Directorate Renewal exercise. The responsibility for the Drugs Directorate and the change process was assigned to the then Assistant Deputy Minister, National Pharmaceutical Strategy (now Executive Director, National Pharmaceutical Strategy). These initiatives were consolidated into the Drugs Directorate Renewal Office reporting to the Executive Director, in order to coordinate the renewal process for the National Pharmaceutical Strategy/Drugs Directorate (NPS/DD).

The NPS/DD Senior Management Review Committee, chaired by the Associate Deputy Minister and comprised of senior management from HC and external interest groups was set up to review and advise on the renewal strategy. The Drugs Directorate Renewal Implementation Strategy is designed to guide the change process, leading to a vital, responsive, dynamic organization which will serve Canadians effectively and efficiently into the 21st century. The strategy was approved by the Minister in August 1993 and management of the Drugs Directorate and the change process was assigned to the Executive Director NPS/DD.

The Renewal exercise is based on a series of almost sixty projects. For each project, a written description outlines the objective, approach, potential impact, milestones, and resources required. Project leaders have been designated, a reporting system is in place, and mechanisms for stakeholder consultation have been established. Some projects are complete and the majority were to finish within 1994. Recommendations 7.4-7.7 of Review Team 7 (Drugs) have been incorporated into the Drugs Directorate Renewal Implementation Strategy. Therefore, no further discussion of this topic will be provided herein. For further information regarding the implementation of these recommendations contact:

Mrs. B.J. Benning
Renewal Coordinator
Drugs Directorate
Room 139, HPB Building
Tunney's Pasture
Ottawa, Ontario K1A 0L2
Tel: 613-957-0370
Fax: 613-941-6955

Notwithstanding the above, two additional topics which overlap with the food regulations were addressed by Review Team 7.

First, regarding recommendation 7.6(g), the Expert Advisory Committee on Herbs and Botanical Preparations was reconvened on June 22-23, 1993. The Second Report of the Expert Advisory Committee on Herbs and Botanical Preparations was published on February 2, 1994 and will be considered in finalizing proposed regulatory controls on such products. This initiative was

announced in the ***Federal Regulatory Plan 1995*** as HCan/95-25-O-I Herbs and Botanical Preparations (p. 88).

Second, recommendation 7.7(f) suggested that Canada adopt, by reference, the United States or European standards/regulations for products of biotechnology. Action on this recommendation is being taken as part of the initiative announced in the ***Federal Regulatory Plan 1995*** as HCan 95-21-N-I Regulation of Novel Foods and Novel Food Processes (p.86).

These latter initiatives fall outside the scope of the Regulatory Review and will not be discussed further in this document. For more information, contact Dr. Frank Welsh, Bureau of Food Regulatory, International and Interagency Affairs, Tel: 613-957-0188, Fax: 613-941-3537.

BRANCH LEVEL INITIATIVES

Certain recommendations from the Regulatory Review will be implemented as part of existing larger HPB initiatives (e.g., revenue generation, development of a HPB inspection policy, etc.). Information may be obtained from HPB contacts indicated herein.

Other recommendations referred to new issues for examination pertaining to the Regulatory Process in general rather than to specific regulations. Recommendations 7.1, 7.2 and 7.3 were raised by Review Team 7 and include: the use of information letters, consultation mechanisms, periodic Regulatory Review, Branch appeal mechanisms, and how to improve communication with the Branch. These issues apply across Directorates, even though they were identified by Team 7 only. Additionally, these issues have been discussed at both Regulatory Review Advisory Committee meetings and represent longstanding concerns of stakeholders with respect to "process" of government rather than the creation or maintenance of the regulations per se. These issues will be reviewed and Branch policies developed and communicated to stakeholders. For more information contact:

Mr. Barry Sterparn
Director
Office of Policy and Scientific Affairs
Health Protection Branch
Room 1700, Jeanne Mance Building
Tunney's Pasture
Ottawa, Ontario K1A 0L2
Tel: 613-954-3006
Fax: 613-954-9981

CONSULTATION

In the spring of 1994, Health Canada distributed, for comment, ***Draft Volume Three: Proposed Implementation Plan*** to approximately 250 national and regional food trade associations, federal and provincial government departments with food responsibilities, consumers' associations, academia, and health professional associations.

Twenty-two aggregate and individual responses were received. In general, comments supported the direction of the proposed implementation, with some clarification of issues requested. In some instances, new issues were raised which were, where possible, incorporated into existing Regulatory Review projects and where required, new projects were initiated. Significant comments were received with respect to projects on the addition of nutrients to foods, issues surrounding advertising, and communication of policy decisions to stakeholders. Appropriate actions to best address these concerns have been incorporated into the implementation plan or will be incorporated into the standard operating procedures for the Food Directorate Regulatory Process.

A Regulatory Review Advisory Committee composed of members of senior management of HPB and the food, drugs, and medical devices industries and representatives of consumers associations and health professionals was established in April 1993. The Committee provided its views on the initial issues papers that were sent to stakeholders and identified the priorities, problems, and themes that were to be explored in the external consultations. The Committee first met on May 27, 1993 to give comments and advice on the final report (***Volume 1***). A second meeting was held June 16, 1994 to discuss regulatory priorities, processes and communications. Final concurrence with the overall direction of implementation was obtained.

The Food Directorate of HPB has initiated action on certain recommendations for which there is believed to be broad support from stakeholders (e.g., the Interim Marketing Authorization (IMA), p.1-5 and revocation of obsolete regulations, pp.3-4, 4-2, and 5-2). Consultation documents providing further detailed proposals on the implementation of other recommendations will be distributed to stakeholders for comment.

COMMUNICATION

Improvements in methods of HPB communication with stakeholders have occurred over the past few years. The Food Directorate has developed the electronic version of the ***Food and Drugs Act and Regulations*** and the overnight fax abstract service of the ***Canada Gazette Part I and Part II***. For information contact Gary Trivett (see address below).

Issues regarding communications were discussed in ***Volume 1*** (p. 68). The proposal to improve the index to the ***Food and Drug Regulations*** (Rec. No. 7.1(a)) is being investigated. The publication of the Regulations on CD-ROM or on computer diskette (Rec. No. 7.1(c)) was not feasible and resulted in the creation of the on-line electronic version of the ***Food and Drugs Act***

and Regulations. Alternative methods of communication are being considered (e.g., Bulletin Board System (BBS), a local telephone number, notification of major trade journals of regulatory changes and progress, Regulatory Affairs newsletter).

The Regulatory Review is a major initiative which will require active communication with stakeholders and follow-up with all interested parties; dissemination of information is critical and could contribute to enhanced public protection and industrial competitiveness. Sharing of government information via the Internet and other electronic means is becoming increasingly common. Thus, communication of progress of the Regulatory Review will employ a variety of methods.

ELECTRONIC ACCESS TO THE REGULATORY REVIEW *UPDATE*

Project Leaders will enter data into the Regulatory Review Reporting System and a report entitled the Regulatory Review *UPDATE* will be periodically posted to the HPB file server. In this way, stakeholders may obtain access to the information relevant to any specific project (see Appendix for details). The use of this system for communication with stakeholders is expected to evolve as users make increased use of the system. As a result of this initiative, stakeholders should spend less time in obtaining information and the most up-to-date information will be continually available.

The Regulatory Review *UPDATE* will be maintained throughout the Regulatory Review process. A Regulatory Review mailing list to support normal mail and telephone communication with stakeholders will continue to be maintained. A Regulatory Review mailing list for communication with stakeholders with electronic communication facilities (fax, e-mail) will also be established. To assist in compiling these mailing lists, please complete and return the Communications Survey found as Appendix VII.

Stakeholders have the following four options for electronic access to the Regulatory Review *UPDATE*:

- the HPB BBS (Bulletin Board System)
- the World Wide Web (WWW)
- GOPHER
- Internet Mailing List

For information on how to obtain electronic access to the Regulatory Review *UPDATE*, please see Appendix VI. For additional information, contact:

Mr. Gary Trivett
Food Directorate
Tel: 613-957-1316
Fax: 613-941-3537
Internet: gtrivett@hpb.hwc.ca

HEALTH PROTECTION BRANCH BULLETIN BOARD SYSTEM (HPB BBS)

The HPB BBS is currently carrying information for the Laboratory Centre for Disease Control (LCDC), the Drugs Directorate, and Medical Devices Bureau. It is evolving into a system which would provide a common public access point for public health protection information. Arrangements have been made to add the Food Directorate Regulatory Review *UPDATE* to the existing system.

WORLD WIDE WEB (via Internet)

The WWW is a method of linking together documents on similar subjects using "hypertext" software. These documents may be found on the same file server or on file servers throughout the world, thus providing public access on a myriad of topics. The Regulatory Review *UPDATE* has been added to the HPB file server so that it is accessible via the WWW.

GOPHER (via Internet)

GOPHER is another method of linking file servers in a world wide network (the Internet) and will provide access to the information on the HPB file server including the Regulatory Review *UPDATE*.

INTERNET MAILING LIST

An Internet Mailing List is software which has been designed to manage the administrative function of maintaining a mailing list. Clients may add or remove themselves to and from the list by sending a message (essentially their Internet address) to the List software. The software providing this capability on the HPB file server is called "Majordomo". Periodically, the Regulatory Review *UPDATE* will be posted to Majordomo which will then automatically forward the file to those on the mailing list.

FORMAT OF VOLUME 3

The specific recommendations of each review team are addressed in separate chapters of this volume. In each chapter, the recommendations are grouped according to:

1. Regulations that were recommended for retention;
2. Recommendations that have been rejected;
3. Recommendations that have been reviewed and action completed;
4. Recommendations already in the regulatory process or that are part of larger HPB initiatives;
5. Regulations recommended for revocation;
6. Recommendations for regulatory amendments; and
7. Recommendations for policy development.

For recommendations that fall within the first five groupings above, paragraphs are provided that describe the rationale for the decision or the action to be taken. Mailing addresses for relevant government offices are provided in Appendix VIII.

For groups 6 and 7, project sheets that describe the proposed initiatives are provided in the Annexes to each chapter. The Project Descriptions contain a number of terms which are defined below.

COMPLEXITY:

Complexity refers to the level of activity that will be required to complete the project. It has been subdivided into five categories:

1. (Immediate-1) - no review required, move directly to ***Canada Gazette Part I*** (prepublication) or write policy position, e.g. obsolete regulations or minor housekeeping amendments

2. (Immediate-2) - final internal review of an initiative already in progress and near completion, then send to ***Canada Gazette Part I*** or write policy position

3. (Short term) - relatively straight forward review required, routine consultation and send to ***Canada Gazette Part I*** or write policy position

4. (Medium term) - more complicated review required, more extensive consultation

5. (Long term) - major review and consultation required

A number of criteria were used in determining the overall complexity or difficulty in completing a project. These include: the degree of risk to the public and how clearly the risk is defined, the controversial nature of the issue, the clarity, strength and mass of available science supporting the proposed action, the type and level of consultation required, the necessity of ensuring the public safety, and the potential impact on competitiveness of Canadian industry.

PRE-PUBLICATION/PUBLICATION:

The estimated date of publication of a proposed regulatory amendment for consultation purposes in ***Canada Gazette Part I*** or the publication of a HPB policy paper.

RECOMMENDATIONS:

This heading indicates the number of the recommendation as it is found in Chapter 5 of ***Volume 1***. The page number in brackets indicates where the recommendation is found in ***Volume 2***. For example, recommendation 1.2 (1-34) resulted from Review Team 1, Recommendation 2 and is discussed in the Report of Review Team 1, page 34 of ***Volume 2***.

TEAM 1

ADMINISTRATION, INSPECTION AND ENFORCEMENT

Team 1 reviewed the ***Food and Drugs Act and Regulations*** with respect to the authority to promulgate and enforce regulations concerning the appropriate safety and efficacy aspects of foods, drugs, cosmetics and medical devices. A number of recommendations were made regarding the operation and responsiveness of the regulatory process, enforcement, inspection and imports, including specific alternatives to the existing regulatory mechanisms. Eight issues papers were developed resulting in nine recommendations. Many of the initiatives addressed below could lead to major restructuring of the Regulatory Process with significant effects on all three factors which affect competitiveness, that is, responsiveness, harmonization and simplification.

1.1 REGULATIONS THAT WERE RECOMMENDED FOR RETENTION

No recommendations were made in this context.

1.2 RECOMMENDATIONS THAT HAVE BEEN REJECTED

No recommendations were rejected.

1.3 RECOMMENDATIONS THAT HAVE BEEN REVIEWED AND ACTION COMPLETED

No recommendations fell into this group.

1.4 RECOMMENDATIONS THAT ARE PART OF LARGER HPB INITIATIVES

Development and Communication of a HPB Inspection Policy (1.2)[1]

Health Canada is clearly identified as having the primary focus for health and safety issues. Current interdepartmental inspection initiatives include the development of Good Manufacturing Practices (GMP) Regulations by HC and an audit protocol. For foods, initiatives also include: the

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[1] Recommendation number from Chapter 5, *Volume 1* of *A Strategic Direction for Change*, HPB, 1993.

interdepartmental Common Inspection Approach, the Quality Management Program (QMP) of DFO, the Food Safety Enforcement Program (FSEP) of AAFC, and the Canadian Food Inspection System initiative. These latter items are being developed by joint federal, provincial and municipal committees.

Future HC inspection policies or work specifications should be consistent with federal and provincial harmonized inspection initiatives currently under development. To increase regulatory harmonization, HC should develop inspection standards for health and safety which are equivalent to applicable quality management standards recognized nationally and internationally. This project will involve the development and communication to stakeholders of a HPB policy regarding monitoring and inspection activities by HC. The benefits derived should include uniformity of requirements between federal and provincial regulations and international quality systems. For more information contact: Mr. Barry Sterparn, Director, Office of Policy and Scientific Affairs, Health Protection Branch, Tel: 613-954-3006, Fax: 613-954-9981.

Revisions to the Food and Drugs Act - Miscellaneous Concerns (1.3)

Recommendation 1.3 proposed the improving on or moving some definitions in the Act to the regulations and to act on specific miscellaneous concerns identified in the 1984 Consultant Report on the Necessity and Feasibility of Revising the Food and Drugs Act by Mr. R.O. Read (see Vol. 2, p. 1-13). The study by Mr. Read highlighted five areas of concern with respect to the ***Food and Drugs Act***. A review of these issues in consultation with Departmental Legal Services will be conducted with a view to finding the most practical resolution to these issues.

Revision of the Food and Drug Definitions in the *Food and Drugs Act* (Health Claims) (1.3)

Improving or moving some definitions in the Act to the regulations was recommended by Review Team 1. Subsequent comments were received that the definitions of "food" and "drug" are too restrictive in the areas of health claims, labelling and advertising and that some way of liberalizing the use of claims should be investigated.

A HPB working group has reviewed the definition of a drug and with the concurrence of the NPS/DD Senior Management Review Committee has accepted the current definition. The working group, after comparison with definitions of other countries, did not agree that the definition is too broad, but that the definition is not sufficiently precise to differentiate categories of products including drugs, food, cosmetics, etc. Copies of the report of the review are available from the Drugs Directorate Renewal Office, Tel: 613-957-0370, Fax: 613-941-6955.

Over the years, there have been numerous requests to change the definition of a food. Currently, foods which carry "drug-like" or "health" claims are considered to be drugs under the definition of a drug or are prohibited under Section 3 of the ***Food and Drugs Act*** by references to Schedule A diseases.

The consensus of the Regulatory Review Advisory Committee was that it is unclear whether fundamental change of the definitions in the ***Food and Drugs Act*** is required and that revision of the Act should not be pursued at this time. Alternatively, health claims will be reviewed as the next logical step in the current review of Nutrition Labelling and Claims which was initiated in December 1993 (see also p.4-2). A legal opinion will be sought to determine the possible options available under Section 3 of the ***Food and Drugs Act*** and in consideration of the "health" claims which have been approved by the U.S. FDA. For further information contact: Dr. Margaret Cheney, Nutrition Evaluation Division, Food Directorate, Tel: 613-957-0352, Fax: 613-941-6636.

Revenue Generation (Fee Structures) (1.4)

This initiative was to examine the feasibility of cost recovery in harmonization with other federal departments and could include levying of fees for the licensing or registration of firms, the assessment of products and labels, the issuance of export certificates and certification and licensing of importers. The HPB Executive Committee is finalizing the Health Protection Branch Cost Recovery and Client Fee Policy, which will guide the implementation of cost recovery in the Branch. This Policy will be submitted to Treasury Board for review, and will be widely circulated for comment prior to implementation. For more information contact: Mr. Doug Loken, Director, Revenue Generation and Business Planning Office, Management and Program Services Directorate, Health Protection Branch, Tel: 613-957-1799, Fax: 613-954-0716.

Food Import Control 1.5 (1.5.1 to 1.5.6) (1-25)

The Health Protection Branch has a mandate to regulate imported products. In the food area this responsibility is shared with other government departments, whereas the Branch has the sole responsibility for regulating imported drugs and medical devices. Current import control methods and procedures of all government departments, especially in the food area, are being criticized by domestic producers and importing establishments. The criticisms include lack of control, too much control, non-enforcement of existing import regulations, demands for better import regulations and fair, effective and efficient delivery of the import control function.

In order to promote harmonization in international food trade, much international activity has been devoted to obtaining agreements and negotiating consensus on standards related to food safety, certification, packaging, labelling, etc. Canada is a member of the *FAO/WHO Codex Alimentarius Commission* and has actively participated in the negotiations regarding the GATT (General Agreement on Tariffs and Trade now renamed the World Trade Organization - WTO) which will came into effect in January 1995.

The Regulatory Review made limited recommendations regarding import control. Rather than make piecemeal changes to the system, the Food Directorate is initiating a broader review and will make recommendations for overall improvement of the health and safety risk-based import control program of HC.

This review will be undertaken considering health and safety as well as social and cultural concerns of all Canadians. The first step will involve an analysis of the import sector to quantify what is imported and from where, to identify trends, resources currently employed, international constraints and obligations, and importing practices of other nations. The Regulatory Review recommendations on Import Control (1.5), Import Control of Veterinary Drugs, p. 2-9, Enforcement of Regulations Concerning Imported Irradiated Food, p. 2-4, Extraneous Material Guidelines, p. 5-4, and Regulations Concerning Low Acid Food in Hermetically Sealed Containers, p. 5-4 will be considered within this context.

A variety of options will be considered including legislative or regulatory changes, administrative changes, and interdepartmental and international agreements. Following consultation with all stakeholders and a review of recommendations a strategic plan for an improved food import control program will be published and implemented. This initiative will require particularly close interdepartmental consultation and cooperation between HC, AAFC, DFO, IC, and Revenue Canada (Customs). Consultation with legal services, provincial governments, import associations, national and regional food industry associations, and consumer associations will also be necessary. For more information contact: Mr. Peter Pauker, Food Import Control Program Officer, Food Directorate, Tel: 613-957-3838, Fax: 613-941-3537.

Development and Communication of a HPB Compliance Policy (1.6)

HPB is responsible for enforcement of health and safety matters under the legislative authority contained in Part I and II of the ***Food and Drugs Act***. Stakeholders have identified occurrences of inconsistent and inequitable application and enforcement of the regulations. HPB will develop a compliance policy that considers stakeholder recommendations outlined in ***Volume 1*** (Rec. 1.6). Existing HPB compliance documents and guidelines, as well as those from other regulatory agencies, will be reviewed in developing this policy. The benefits derived should include a "level playing field" with uniformity of compliance and enforcement application across commodity groups for both imported and domestic products. A comprehensive HPB compliance policy, including enforcement, which is applied in a uniform and equitable manner and communicated to all interested parties will be developed. For more information contact: Mr. Barry Sterparn, Director, Office of Policy and Scientific Affairs, Health Protection Branch, Tel: 613-954-3006, Fax: 613-954-9981.

1.5 REGULATIONS RECOMMENDED FOR REVOCATION

No revocations were recommended.

1.6 RECOMMENDATIONS FOR REGULATORY AMENDMENTS

The following regulatory amendments were recommended by Team 1 and are addressed in Annex 1 to this chapter:

- Interim Marketing Authorization (IMA) (1.7, 2.4, 4.3)

- Restructuring the Food Additive Tables (1.9) - see Food Additive Tables and GMP Listings, p. 4-6.

1.7 RECOMMENDATIONS FOR POLICY DEVELOPMENT

The following recommendations are addressed in the project sheets contained in Annex 2 to this chapter:

- Rationalization/Harmonization of Food Standards (1.1, 1.8, 4.11)

- Fast Track Evaluation (FTE) (1.7)

ANNEX 1

PROJECT DESCRIPTIONS FOR REGULATORY AMENDMENTS

ADMINISTRATION, INSPECTION AND ENFORCEMENT

PROJECT: Interim Marketing Authorization (IMA)	**COMPLEXITY:** 2
PROJECT LEADER: Ron Burke **Tel:** 613-957-1750 **Fax:** 613-941-3537	**START DATE:** October 1993
PROJECT TEAM: BFRIIA, HPB Legal Services	**PRE-PUBLICATION:** End 1994
RECOMMENDATIONS: 1.7 (1-47), 2.4 (2-74), 4.3 (4-38)	**REGULATIONS:** New Regulation

OBJECTIVE	To expand the Temporary Marketing Authorization (TMA) concept to allow a food not in compliance with the Regulations to be marketed while an amendment to permit its on-going legal sale is being processed.
BACKGROUND	Changes to regulations relative to ingredients in standards, food additives, residues of agricultural chemicals and veterinary drugs, and addition of nutrients lost during processing require that the proposal be processed through the regulatory amendment procedure which can take a minimum of six months and sometimes considerably longer to be published in ***Canada Gazette Part II***. Currently, this applies to all of the above regardless of whether a substance would be a new addition to the food supply or is already permitted in other foods. This is a major impediment to industry and consumers by delaying marketing of new products for considerable periods of time.
APPROACH	Generally, all foods sold in Canada must be in compliance with the ***Food and Drug Regulations***. However, Sections B.01.054 and B.01.055 specify conditions under which a Letter of Temporary Marketing Authorization may be issued which allows a manufacturer or distributor to sell a food (not in compliance) for a limited period of time and under strictly defined conditions to "generate information in support of an amendment to the Regulations". The Interim Marketing Authorization (IMA) procedure would allow the sale of products which have been thoroughly evaluated and for which no health, safety or nutritional risks to the public have been identified. The IMA would thus bridge the time between completion of a scientific evaluation and publication of the appropriate regulatory amendment. The IMA proposal is undergoing legal review.
CONSULTATION	Strongly supported by industry during Phase I. Consultation with other federal departments, provincial governments and consumers.
IMPACT	Industry would be more competitive and consumers would benefit through earlier availability of new products.
DEPENDENCY	Independent

ANNEX 2

PROJECT DESCRIPTIONS FOR POLICY DEVELOPMENT INITIATIVES

ADMINISTRATION, INSPECTION AND ENFORCEMENT

PROJECT: Rationalization/Harmonization of Non-Health Related Food Standards	**COMPLEXITY:** 5
PROJECT LEADER: Greg Borotsik **Tel:** 613-957-0189 **Fax:** 613-941-3537	**START DATE:** January 1994
PROJECT TEAM: BFRIIA, AAFC, DFO	**PRE-PUBLICATION:** TBA
RECOMMENDATIONS: 1.1, 1.8 (1-54), 4.11 (4-59)	**REGULATIONS:** All food standards in federal regulations

OBJECTIVE	To review and evaluate all federal non-health related food standards (identity/composition) and determine the most effective and efficient mechanism for presenting them in federal legislation. In those instances where a unique Canadian standard is not indicated, the applicable Codex Alimentarius standards could be referenced as the Canadian standard.
BACKGROUND	Thirty years ago, food standards were used as a primary method of controlling the quality and safety of foods. Today, the bulk of the food products in the marketplace are unstandardized and since 1976, all unstandardized foods (with the exception of alcoholic beverages) must carry a list of ingredients on the label. Therefore, the rationale for food standards has changed in that the standards are now more applicable to foods that are used in the manufacture and processing of more innovative unstandardized products. The Labatt Lite Beer Decision of the Supreme Court of Canada in 1979 made it clear that food standards promulgated as regulations under the ***Food and Drugs Act*** could not be supported under the Criminal Law power. As a consequence, the amendment to Section 6 of the Act in 1987 resulted in a situation where a product standardized under the ***Food and Drugs Act*** must cross a provincial border or be imported into Canada before the standard would be operative. The introduction of the "Trade and Commerce Limitation" into the Act resulted in a *de facto* duplication of the authority used for promulgation of related standards under the ***Canada Agricultural Products (CAP) Act***, the ***Meat Inspection Act*** and the ***Fish Inspection Act***. The Labatt Lite Beer Decision did not jeopardize the health-related aspects of food standards in the ***Food and Drug Regulations*** and as such, these provisions are applicable and enforceable regardless of the level of sale that takes place. For example, the food additive provisions in a food standard are operative even if the product is sold only within a province.

APPROACH	The approach will involve the identification of duplicate non-health related food standards in federal legislation (see project on p. 4-9) followed by an in-depth evaluation of regulatory options i.e. create a central compendium for food standards, revoke federal standards and transfer to the compendium for reference by federal and/or provincial regulatory agencies. This will require consultation with federal and provincial departments involved in food regulation to identify several alternative options and evaluate the impact of changing the present regulatory system regarding food standards. Any options for consideration must be consistent with current regulatory initiatives, food industry realities and not jeopardize the integrity of the Canadian food system.
CONSULTATION	Interdepartmental consultation with federal and provincial food regulators, legal services, industry associations and consumers.
IMPACT	There should be no cost to the stakeholders; the ultimate regulatory system will become more transparent, more "user friendly" and flexible and facilitate Canada's competitive trade position.
DEPENDENCY	Coordinate with Duplicate Food Standards, p. 4-9 and Food Additive Tables & GMP Listings, p. 4-6

PROJECT: Fast Track Evaluation (FTE)	**COMPLEXITY:** 2
PROJECT LEADER: John Salminen **Tel:** 613-957-1700 **Fax:** 613-990-1543	**START DATE**: January 1994
PROJECT TEAM: Chemical Evaluation Division	**PUBLICATION:** TBA
RECOMMENDATIONS: 1.7 (1-53)	**REGULATIONS:** Division 16

OBJECTIVE	To establish a Fast Track Evaluation (FTE) scheme for "minor use" food additive submissions and to develop eligibility criteria for such submissions.
BACKGROUND	The current regulatory approach requires that "minor use" submissions undergo the same treatment as a major submission. These minor extensions of use often do not appreciably increase the substance's probable daily intake and there are often no outstanding toxicological concerns. The FTE process would allow the accelerated evaluation of food additives which are already in use for use in other foods and for minor increases in the level of use in existing foods. As such, these submissions could be "fast tracked" with minimal further evaluation.
APPROACH	This policy will be most useful during the period in which the Food Additive Tables are being restructured (see Food Additive Tables and GMP Listings, p. 4-7). The criteria for FTE eligibility include: • no new or outstanding toxicological concerns (adequate toxicological database) • unlimited ADI or no increase in daily intake or increase above the ADI (Acceptable Daily Intake) • available efficacy data is sufficient • meets acceptable specifications • available methodology is useable in the new application • standards issues must not be raised or the use contravene existing standards. Following approval of a submission, the petitioner will be advised of the decision to recommend a revision of the regulations to provide for the use outlined in the submission.
CONSULTATION	The policy has been approved within the Food Directorate and is being implemented.
IMPACT	The time between submission and receipt of approval by the applicant will be reduced, while maintaining consumer protection.
DEPENDENCY	Coordinate with Interim Marketing Authorization, p. 1-7.

TEAM 2

FOOD CHEMISTRY - CONTAMINANTS

Team 2 was given the task of reviewing the Sections of the ***Food and Drug Regulations*** dealing with chemical contaminants, agricultural chemicals, veterinary drugs, food packaging materials and food irradiation. Six issues papers were developed by this team, and subsequent discussions resulted in nine recommendations which are addressed below. The use of an amended Temporary Marketing Authorization for agricultural chemicals is being addressed by the Interim Marketing Authorization proposal (p. 1-7) and should result in a significant improvement in responsiveness of the Regulatory Process.

As a result of comments received from the Canadian Animal Health Institute (CAHI) projects on the Advertising of Veterinary Drugs and on Import Control of Veterinary Drugs were added (see pp. 2-9 and 2-10).

2.1 REGULATIONS THAT WERE RECOMMENDED FOR RETENTION

The following sections of the Regulations were recommended for retention, and the recommendations were accepted:

Division 15
- Regulations and tables for Veterinary Drugs and Agricultural Chemicals (2.1)[3]
- The current control mechanisms for Food Chemical Contaminants (2.5) including Administrative Guidelines

Division 23 Continuation of voluntary pre-market notification for food packaging materials (2.7)

Division 26 Retention of the regulations concerning food irradiation (2.9)

2.2 RECOMMENDATIONS THAT HAVE BEEN REJECTED

The following recommendations were reviewed by the lead agency and rejected:

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[3] Recommendation number from Chapter 5, ***Volume 1*** of ***A Strategic Direction for Change***, HPB, 1993.

Food Packaging Materials (2.8)

This proposal recommended the establishment of new regulations requiring food manufacturers to provide evidence, on demand, to support the safety of the food packaging materials they are using. The existing approach allows considerable flexibility to the food industry and is considered to provide the consumer with safe packaging materials. Therefore, the recommendation to establish new regulations is rejected.

Establish Separate Veterinary Drug Regulations

The Canadian Animal Health Institute (CAHI) has submitted a proposal advocating the establishment of a separate section for veterinary drug regulations. Regulations pertaining to veterinary drugs are found in three locations of the ***Food and Drug Regulations***. First, most of the drug regulations in Part C - Drugs apply to both human and veterinary drugs. Second, sections C.01.600 to C.01.625 contain regulations specific to veterinary drugs. Last, there are regulations found in Part B - Foods which deal with veterinary drug residues in food. Because of the extensive overlap of regulations pertaining to both veterinary drugs and human drugs, a separate division for veterinary drugs would be largely redundant. Therefore, no further action will be taken in this regard.

2.3 RECOMMENDATIONS THAT HAVE BEEN REVIEWED AND ACTION COMPLETED

No recommendations fell into this category.

2.4 RECOMMENDATIONS ALREADY IN THE REGULATORY PROCESS OR THAT ARE PART OF LARGER HPB INITIATIVES

No recommendations fell into this category.

2.5 REGULATIONS RECOMMENDED FOR REVOCATION

No regulations were recommended for revocation.

2.6 RECOMMENDATIONS FOR REGULATORY AMENDMENTS

The projects listed below propose substantial changes to the Regulations that will require significant review and consultation. Descriptions of these projects can be found in the Annex to this chapter.

- Expansion of Table III of B.15.003 (2.2)

- Contaminants (2.6)

- Use of the Temporary Marketing Authorization for Agricultural Chemicals (2.4) (see Interim Marketing Authorization, p. 1-7)

One additional administrative recommendation is described below:

Consolidation of the Regulations Concerning Veterinary Drugs (2.2)

Currently, sections B.14.017 and B.22.009 of the ***Food and Drug Regulations*** prohibit the presence of estrogenic growth promoters such as diethylstilbesterol (DES) in food. Section B.01.048 provides a similar protection with respect to chloramphenicol. Division B.15.003 and Table III establish Maximum Residue Levels (MRLs) for approved veterinary drugs in a variety of foods. There was general support from the focus groups and the stakeholder consultation workshops to relocate the above regulations to Division 15 or to create a separate division for veterinary drugs in the ***Food and Drugs Regulations***. The Canadian Animal Health Institute (CAHI) has submitted a proposal for a separate section for veterinary drug regulations which was addressed in section 2.2 above. However, sections B.14.017 and B.22.009 will be relocated to Division 15 as recommended. Project Leader: Dr. M.S. Yong, Bureau of Veterinary Drugs, Tel: 613-957-3857, Fax: 613-957-3861.

2.7 RECOMMENDATIONS FOR POLICY DEVELOPMENT

The following projects will entail significant reviews of HPB policy. The project descriptions are found in Annex 2 to this chapter.

- Import Control of Veterinary Drugs[4]

- Advertising of Veterinary Drugs[4]

- Review of Regulation B.15.002.(1) (2.3)

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[4] Review requested by Canadian Animal Health Institute during consultation phase.

The following projects will result in changes to policy guidelines that are of a more routine nature:

Packaging Material (Official Methods) (FO-40 & FO-41)(2.7)

The existing Official Methods FO-40 (vinyl chloride, VC) and FO-41 (acrylonitrile, AN) will be evaluated and changes to reflect the capabilities of modern analytical instrumentation will be considered. State of the art technology will be evaluated to determine its suitability as a replacement for existing standard methods. The necessity for validation studies in collaboration with regional laboratories will be considered also. The replacement of present official methods with newer methods using enhanced detection limits may result in the lowering of regulatory detection limits which could necessitate the reformulation of packaging materials to enhance consumer safety. The plastics industry will be consulted via its association. Project Leader: Dr. Denis Page, Bureau of Chemical Safety, Tel: 613-957-0979, Fax: 613-941-4475.

Food Packaging Materials (Recycled Materials) (2.8)

This proposal recommended the development of guidelines for the use of recycled materials that come in direct contact with food. Such guidelines are considered necessary to control the use of recycled materials in food packaging applications and to assist the food packaging industry in making such submissions to the Branch. Current developments in the United States will be examined for applicability to the Canadian situation. Project Leader: Mr. Michel A. Pelletier, Bureau of Chemical Safety, Tel: 613-957-1709, Fax: 613-990-1543.

Enforcement of Regulations Concerning Irradiated Food (2.9)

This proposal addressed the need to improve enforcement capabilities for detecting foods that have been irradiated. Appropriate methodology and instrumentation to monitor certain foods will be investigated. Contracting out for specialized methodology will be considered. Project Leader: Dr. J.F. Lawrence, Bureau of Chemical Safety, Tel: 613-957-0946, Fax: 613-941-4775.

Food Irradiation Education (2.9)

This recommendation proposed the development of a consumer education program concerning irradiated foods. This recommendation was based on the observation that the public had a great deal of misunderstanding and misconception about food irradiation. During Phase I consultations, stakeholders could not reach a consensus as to whose responsibility it was to deliver an education program or provide educational materials. However, an "Issues" document and a resource list concerning food irradiation will be developed and made available to consumers. Project Leader: Dr. Bruce Lauer, Bureau of Chemical Safety, Tel: 613-957-1696, Fax: 613-990-1543.

ANNEX 1

PROJECT DESCRIPTIONS FOR REGULATORY AMENDMENTS

FOOD CHEMICALS AND CONTAMINANTS

PROJECT: Expansion of Table III of B.15.003	**COMPLEXITY:** 3
PROJECT LEADER: Dr. M.S. Yong **Tel:** 613-957-3857 **Fax:** 613-957-3861	**START DATE:** April 1, 1994
PROJECT TEAM: Human Safety Division of BVD	**PRE-PUBLICATION:** September 1995
RECOMMENDATIONS: 2.2 (2-27)	**REGULATIONS:** B.15.003,Table III.

OBJECTIVE	To expand Table III of B.15.003 of the ***Food and Drugs Act and Regulations*** to include other veterinary drugs as part of the on-going harmonization process with the United States under the North American Free Trade Agreement (NAFTA).
BACKGROUND	There is general agreement between Canada and the United States concerning Maximum Residue Levels (MRLs) for those veterinary drugs listed in Table III to B.15.003. There was general support from the focus groups and the stakeholder consultation workshops for the inclusion of additional veterinary drugs in Table III.
APPROACH	MRLs for additional veterinary drugs will be harmonized with U.S.A. and be included in Table III of Division 15 of the ***Food and Drug Regulations***.
CONSULTATION	Consumer associations, industry associations, livestock producers, the Canadian Veterinary Medical Association, federal and provincial regulatory agencies.
IMPACT	Liberalization of trade between Canada and the United States without reduction of consumer protection.
DEPENDENCY	Independent.

PROJECT: Contaminants	**COMPLEXITY**: 5
PROJECT LEADER: John Salminen **Tel:** 613-957-1700 **Fax:** 613-990-1543	**START DATE:** January 1994
PROJECT TEAM: Bureau of Chemical Safety, BFRIIA	**PRE-PUBLICATION:** August 1996
RECOMMENDATIONS: 2.6 (2-43)	**REGULATIONS:** Division 15, B.01.046, B.01.047

OBJECTIVE	To evaluate the current tolerances for contaminants in food in light of available scientific information and to revise, delete or add to and consolidate these provisions in the ***Food and Drug Regulations***.
BACKGROUND	Food chemical contaminants pose a potential risk to human health, thus the exposure to these substances should be minimized. Despite varying opinions about the approach to their regulation expressed during Phase 1 of the Regulatory Review, it was agreed that the existing regulations should be reviewed to ensure that they are relevant, up-to-date, based on current knowledge and that any revision is easy to understand and readily accessible.
APPROACH	A two-phased approach is proposed. Phase one would involve the review of existing regulatory limits with a view toward removing outdated or inconsequential requirements. Phase two would examine consolidation and simplification of the regulations.
CONSULTATION	Companies, industry associations, other federal government departments, provincial governments, consumer groups, importers of food products and major trading partners.
IMPACT	Existing regulations should be simplified, increasing understanding, while maintaining consumer protection.
DEPENDENCY	Independent

ANNEX 2

PROJECT DESCRIPTIONS FOR POLICY DEVELOPMENT INITIATIVES

FOOD CHEMICALS AND CONTAMINANTS

PROJECT: Import Control of Veterinary Drugs	**COMPLEXITY:** 4
PROJECT LEADER: TBA	**START DATE:** December 1, 1994
PROJECT TEAM: Bureau of Veterinary Drugs	**PRE-PUBLICATION:** January 1996
RECOMMENDATIONS: 1.5 (2-27)	**REGULATIONS:** New reg'ns/ policy

OBJECTIVE	To improve the food safety risk-based import control program of HPB for veterinary drugs and chemicals used in animals.
BACKGROUND	HPB has the sole responsibility for regulating imported veterinary drugs. The last few years have seen increased concern about the potential for illegal importation and subsequent distribution and sale of unapproved veterinary drugs and bulk chemical substances for food-producing animals in Canada. As a result, options for improved/stronger regulatory control over imports and fair, effective and efficient delivery of the import control function will be considered.
APPROACH	The feasibility of establishing new regulations or enforcement policy to impose tighter controls on the entry of imported veterinary drugs and bulk chemical substances; the development of better tracking/monitoring systems for the sale of these substances in Canada; and the adoption of stronger punitive actions will be examined taking into consideration the current regulatory context and the input from involved agencies and stakeholders.
CONSULTATION	CAHI, livestock producers, Canadian Veterinary Medical Association, HPB regional staff, provincial veterinary associations, Agriculture and Agri-Food Canada, other federal and provincial regulatory agencies, Customs Canada, Brokers' Association.
IMPACT	Results should include equal treatment of domestically produced veterinary drugs and imported drug substances, reduction of consumer risk associated with drug residues in the food supply, an increase in the Canadian veterinary pharmaceuticals and food industry competitiveness domestically and abroad, and the increased harmonization of the national veterinary drug import program between Canada and the U.S.A.
DEPENDENCY	Coordinate with Import Control, p. 1-3.

PROJECT: Advertising of Prescription Veterinary Drugs	**COMPLEXITY:** 4
PROJECT LEADER: Dr. Lucie Galand **Tel:** 613-957-3867, **Fax:** 613-957-3861	**START DATE:** December 1, 1994
PROJECT TEAM: Bureau of Veterinary Drugs	**PRE-PUBLICATION:** January 1996
RECOMMENDATIONS: from CAHI	**REGULATIONS:** New policy

OBJECTIVE	To conduct a comprehensive analysis of the proposal to advertise prescription veterinary drugs.
BACKGROUND	The Canadian Animal Health Institute (CAHI) has requested that a policy proposal for the advertising of veterinary prescription drugs be published for comment by stakeholders.
APPROACH	The CAHI proposes that advertising copy would be limited to the label text information approved by HPB. A number of factors will need close scrutiny including: the impact on human prescription drugs, practices of trading partners, impact of increased use of anti-microbial drugs and other potential scientific problems. The Bureau of Veterinary Drugs will review this issue in cooperation with the Drugs Directorate and will develop a draft policy which will be distributed to all stakeholders for comment.
CONSULTATION	Canadian Veterinary Medical Association, Center for Veterinary Medicine (U.S.A.), provincial veterinary associations, provincial licensing bodies, all veterinary drug manufacturers, pharmacists, Livestock Publications Council, farm papers, breeders' associations, food producing animal associations, advertising council and agencies, equine, cat, kennel and other companion animal associations.
IMPACT	Advertising of prescription veterinary drugs may result in better informed users and may help to eliminate the potential for harmful residues from livestock food products. The impact on the use of human prescription drugs must be considered.
DEPENDENCY	Independent

PROJECT: Policy Review of Regulation B.15.002.(1)	**COMPLEXITY:** 5
PROJECT LEADER: Dr. B. Huston **Tel:** 613-957-1827 **Fax:** 613-990-1543	**START DATE:** November 1992
PROJECT TEAM: HPB - Chris Warfield, AAFC - Food Inspection Directorate/ Plant Industry Directorate	**PUBLICATION:** TBA
RECOMMENDATIONS: 2.3 (2-72)	**REGULATIONS**: B.15.002(1)

OBJECTIVE	To evaluate the general MRL of 0.1 ppm for agricultural chemicals.
BACKGROUND	Subsection B.15.002(1) of the ***Food and Drug Regulations*** established a default maximum residue limit (MRL) of 0.1 ppm (mg/kg) which has facilitated the control of certain agricultural chemicals in or on food commodities in Canada. This regulation needs to be reviewed with regard to its impact on the competitiveness of Canadian farmers and international trade.
APPROACH	A discussion paper outlining the pros and cons of various options was developed.
CONSULTATION	Consultation with the Canadian Horticultural Council and the farm community is ongoing. Consultation with AAFC, industry organizations, provincial governments, consumer groups, academics, environmental organizations, and health professionals will be undertaken as required.
IMPACT	Revocation of this regulation may affect the competitiveness of Canadian farmers and the availability of certain foods.
DEPENDENCY	Independent

TEAM 3

FOOD LABELLING, PACKAGING, ADVERTISING AND CLAIMS

Team 3, which was composed of members from AAFC, HC, the food industry, the Consumers Association of Canada and the Allergy / Asthma Information Association, reviewed eight areas of the ***Food and Drug Regulations*** regarding food labelling. This review resulted in 35 recommendations on labelling requirements and improvements to the current method of implementing labelling changes. These recommendations are addressed below.

"The consumers right to know is a given." (***Volume 1***, p. 20). Implementation of these recommendations should provide clear, meaningful and adequate information to consumers, as well as flexibility to manufacturers. In particular, the introduction of a single implementation date for food labelling changes would be a significant benefit to industry. The priorities for AAFC Food Division during 1994/95 are 1) revocations, 2) ingredient labelling, and 3) date marking. Projects on country of origin for wines and legibility are scheduled for 95/96.

3.1 REGULATIONS THAT WERE RECOMMENDED FOR RETENTION

The following regulations will be retained, based on the recommendations of Team 3:

B.01.006	Location of Common Name on Label (3.19)[5]
B.01.008(1)(b)(3)(4)(5)(6) **and** **B.01.011**	Manner of Ingredient Declaration (3.7)
B.01.071	Percent of Predominant Nut Declaration on Mixed Nuts (3.21)
B.02.003	Alcohol content on beverage PDP Declaration (3.21)
B.02.021(b)	Label/advertise Highland Whisky with 51% Scottish malt whisky as distilled in Scotland (3.25)
B.02.022(1)	Label/advertise Bourbon whisky (3.25)

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[5] Recommendation number from Chapter 5, *Volume 1* of *A Strategic Direction for Change*, HPB, 1993.

B.02.023[6]	Aging of whisky in wood (3.25)
B.02.033	Composition of imported rum (3.25)
B.02.040(d)[7]	Declare Holland's gin as distilled (3.25)
B.02.040(e)[8]	Blended Declaration on Holland's Gin PDP (3.21)
B.02.043	Age declaration for gin (3.25)
B.02.059[9]	Labelling of blended brandy as imported (3.25)
B.02.061[10]	Declaration of age of brandy (3.25)
B.08.031(b)	Source of milk for cheese declaration (3.21)
B.14.019 (1)(a)(b)	Declaration of selling price and additional charges on meat carcass (3.25)

3.2 RECOMMENDATIONS THAT HAVE BEEN REJECTED

No recommendations were rejected.

3.3 RECOMMENDATIONS THAT HAVE BEEN REVIEWED AND ACTION COMPLETED

The recommendations listed below have been assessed. The current status of each recommendation is given.

Milk Fat Declaration (3.22 (3-115))

Current dietary recommendations and nutrition education programs focus on the percentage milk fat declaration in dairy products. These programs have taught the consumer to use the percentage

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[6] This regulation replaces the previous section B.02.012 which was revoked by Schedule 757, March 23, 1993.

[7] This regulation replaces the previous section B.02.040(a)(b) which was revoked by Schedule 757, March 23, 1993.

[8] This regulation replaces the previous section B.02.040(c) which was revoked by Schedule 757, March 23, 1993.

[9] This regulation replaces the previous section B.02.057 which was revoked by Schedule 757, March 23, 1993.

[10] This regulation replaces the previous section B.02.052 which was revoked by Schedule 757, March 23, 1993.

milk fat information to make heathy food choices from the dairy products group. The replacement of the percentage milk fat declaration with one which uses grams of fat per serving would necessitate a revision of these programs to re-educate the public with respect to this message.

The amendment to replace the current percent milk fat declaration with a declaration of grams fat per serving was favoured and put forward by some industry members and supported by a consumer group. It was believed that the declaration of both percentage fat and grams of fat per serving, as in nutritional labelling, was potentially confusing to consumers.

In the recent consultation on Regulatory Review, the National Dairy Council stated their opposition to this amendment, and there was no support from any other parties for proceeding. Therefore, no further action is contemplated with respect to this recommendation.

Iodide in Salt (3.24)

The recommendation was to re-examine the current requirement to label iodized salt products as containing iodine (B.17.003) for relevancy, clarity and consistency. Iodine is added to table salt (and salt for household use) to prevent iodine deficiency. It is listed on the label as an ingredient and on the PDP to clearly inform the consumer of the presence of iodine. This regulation will be retained.

Claim for the age of rum (3.25) (old B.02.032)

Comments during Regulatory Review Phase 1 recommended retention of this section. Old section B.02.032 was revoked by Schedule 757 published in *Canada Gazette Part II* on March 23, 1993. No additional action will be taken at this time.

Kosher Declaration (3.26) (B.01.049)

Section B.01.049 was promulgated in the 1970's to ensure that food labels did not bear the declaration "kosher" unless they met the requirements of the kashruth. The recommendation from Phase 1 was to reassess this regulation with a view to developing guidelines to be included in the ***Guide for Manufacturers and Advertisers***. It has been subsequently determined that maintaining this regulation is the most appropriate mechanism to ensure proper use of the symbol for kosher foods.

Quantitative Statement on Food Additives (3.24) (B.16.001)

The recommendation from Phase 1 was to reassess this regulation. It has subsequently been determined that this regulation should be retained.

3.4 RECOMMENDATIONS ALREADY IN THE REGULATORY PROCESS

The recommendations addressed below are currently part of the ongoing Regulatory Amendment Process and will not be addressed further within the Regulatory Review framework:

Pre-packaged Water and Ice (Division 12):

Three recommendations addressed this requirement:

- **Ozone in Water & Ice (3.29)** - to consider revoking the requirement to declare the use of ozone when used as a processing aid for water and ice (B.12.002);
- **Fluoride Declaration on Water & Ice (3.30)** - to consider the continuing need for fluoride declaration in waters to which fluoride has not been added (B.12.002(c)); and
- **Location of Mandatory Information on Water & Ice (3.31)** - to consider permitting the use of alternative locations on the package for certain information that is required to be on the PDP.

This initiative is being addressed by Schedule 857 (currently in Step 1) and was announced in the ***Federal Regulatory Plan 1995*** as HCan/95-23-O-I Bottled Water (p. 87).

3.5 REGULATIONS RECOMMENDED FOR REVOCATION

Projects for the revocation of the following group of regulations will be initiated in October 1994 with an estimated pre-publication date of on or before September 1995.

B.01.005	Prohibition Against Placement of Mandatory Information on Bottom of Container (3.2)
B.01.008(1)(a)	Grouping of Mandatory Information with Ingredients (3.3)
B.01.100 (4)(a)(b)	Revoke the need to declare the absence of meat and poultry in simulated meat and poultry products (3.23)
B.08.032	Moisture in Cheese Declaration (3.23)
B.11.015	Tomato Trimmings in Catsup Declaration (3.23)
B.11.105	Antioxidant Addition to Frozen Fruit Declaration (3.23)

B.13.001(g) **B.13.005(e)**	Declaration that gamma irradiated flour and whole wheat flour is "treated" with ionizing radiation (3.24). It has been determined that revocation of these requirements are appropriate as the labelling of irradiated foods is already regulated by B.01.035.
B.13.028	Brown Bread Labelling (3.23)
B.14.031 (f)(g)(gg)	Declaration of the Flavouring of Preserved Meat on the PDP (3.23)
B.14.032(d) (xii)(xiv)(A)(B)	Flavouring of Sausage Declaration on the PDP (3.23)
B.17.001(2)	Free-running Salt Declaration (3.23)
B.21.006(g)	Declaration of Flavouring Added to Fish (3.23)

Projects for the revocation of the following group of regulations will be initiated as per the noted project sheet.

B.01.007 (3)(c)(d)	Exemption from the Identification of a Durable Life Date for Doughnuts and Commissary Products (3.14) (see Date Marking, p. 3-14)
B.02.034	Rum from Commonwealth Caribbean Countries (3.26). After promulgation of section B.02.034 in 1989, the Standing Joint Committee for the Scrutiny of Regulations questioned whether authority existed under the ***Food and Drugs Act*** to put in place a regulation to facilitate the marketing of Commonwealth Caribbean rum in Canada. This regulation may be revoked following consultation with the Departments of National Revenue and Foreign Affairs regarding amendments to the ***Importation of Intoxicating Liquor Act*** (see Miscellaneous Optional Labelling Requirements, p. 3-20).
B.14.016	Horsemeat Declaration (3.23) - Revocation of this regulation is dependent upon amending section B.01.003 which requires that horsemeat carry a label (see Ingredient Declarations on Food Labels, p.3-10)

3.6 RECOMMENDATIONS FOR REGULATORY AMENDMENT

The projects described in this section will require substantial changes to the Regulations and significant review and consultation. These changes are based on the possibility of regulating "differently" in order to provide increased flexibility to industry to enhance competitiveness, while

maintaining health and safety and promoting honesty in the marketplace. Lead agency for all projects is the Food Division, Food Production and Inspection Branch, Agriculture and Agri-Food Canada. The following projects are described on the project sheets contained in Annex 1:

- Legibility of Mandatory Information (3.1)
- Ingredient Declarations on Food Labels (3.4 - 3.6, 3.8 - 3.13, 3.23, 3.24, 3.29)
- Date Marking (3.14 - 3.17)
- Common Name (3.18, 3.20)
- Miscellaneous Mandatory Labelling Requirements (3.24)
- Country of Origin for Wine and Brandy (3.24)
- Miscellaneous Optional Labelling Requirements (3.26 - 3.28)

One additional regulatory proposal was viewed as being less complex and is described below:

Bulk Beef Advertisements (3.22)

This housekeeping amendment will require the declaration of grade and class designation in bulk beef advertisements, and represents the harmonization of the ***Food and Drug Regulations*** with the ***Livestock Carcass Grading Regulations***. This amendment will be grouped with the revocation projects and will be initiated in October 1994 with an estimated prepublication date of on or before September 1995.

3.7 RECOMMENDATIONS FOR POLICY DEVELOPMENT

Policy development proposals addressed ongoing initiatives regarding food labelling and are described below:

Principles Guiding Development of Food Labelling Regulations:

The following two recommendations address the need for changing the approach to developing food labelling regulations:

- Presentation of Labelling Regulations (3.32)
- Consultation on Labelling Issues (3.33)

Throughout the course of Regulatory Review implementation every attempt will be made to write or revise regulations to improve their clarity. Approaches to grouping of labelling regulations and the use of tables will be examined concurrently with Health Canada's overall commitment to simplify the ***Food and Drug Regulations***.

Improved Labelling System: (3.34)

For more information contact: Ms. Rhea Reevie, Food Division, Tel: 613-952-8000 (3792), Fax: 613-952-7387.

1. Single Implementation Date

During Phase 1 of Regulatory Review, concerns were expressed by industry that new regulations were published continuously which required frequent label changes. It was felt that government should, therefore, ensure that a single implementation date be set for all amendments to the regulations requiring label changes within a given period. Subsequently, industry requested a "rolling window" approach to allow changes to be phased in. It is therefore decided that an effective date would be given when the regulations are promulgated to provide manufacturers and importers with sufficient lead time (e.g. 18 months) to revise their labels. Compliance could begin immediately, however, or occur anytime up to the effective date. After the effective date all domestic production and products being imported for sale in Canada would be expected to be in compliance. Products manufactured in Canada or imported prior to the effective date would be allowed to continue through the distribution system, assuming the situation is reasonable.

2. Periodic Review/ Sunsetting

During Regulatory Reviews done by Consumer and Corporate Affairs and Agriculture Canada, "sunsetting" to require a systematic periodic review of various regulations was recommended. With further evaluation, it has been determined that the principle of sunsetting may be inappropriate in many circumstances and may not be the most effective method of ensuring periodic review of the regulations. Any proposals regarding this aspect will, however, be addressed during consultations on specific labelling issues and final positions will be addressed in the Regulatory Impact Analysis Statement.

Labelling Research (3.35)

The proposal was to consider conducting research regarding consumers' needs and understanding, particularly in the area of ingredient labelling. Consumers have considerable interest in food labelling, but research suggests that there may be a lack of understanding and ability to use the information. The GPMC survey "Grocery Attitudes of Canadians" identified ingredient labelling as one of the top four labelling priorities for consumers. In a recent study of consumer use and understanding of nutrition information on food package labels conducted by the National Institute of Nutrition, four out of five considered the list of ingredients to be important information in

selecting foods. A key criticism was complexity and lack of clarity of the information presented.

There appears to be relatively little consumer research on certain labelling areas such as ingredient declaration. Research carried out by industry , however, has not yet been reviewed. This project will start with a review of the literature and industry survey data where available. If needed, qualitative focus group studies and quantitative research with industry and university partners will be considered. Also, the effect of the literacy of the Canadian population will be examined. For more information contact: Ms. Pat Steele, Food Division, Tel: 613-952-8000 (3800), Fax: 613-952-7387.

ANNEX

PROJECT DESCRIPTIONS FOR REGULATORY AMENDMENTS

FOOD LABELLING, PACKAGING, ADVERTISING AND CLAIMS

PROJECT: Legibility of Mandatory Information	**COMPLEXITY:** 4
PROJECT LEADER: Sue Lee-Spiegelberg **Tel:** 613- 952-8000 (3798) **Fax:** 613- 952-7387	**START DATE:** April 1995
PROJECT TEAM: AAFC, IC, HC, Food and Drugs Directorates, HPB	**PRE-PUBLICATION:** November 1996
RECOMMENDATIONS: 3.1 (3-19)	**REGULATIONS:** A.01.016

OBJECTIVE	To examine the feasibility of developing a legibility test to administer the requirements of section A.01.016 to ensure that mandatory information is prominently and clearly displayed and readily discernible to the consumer.
BACKGROUND	Administratively, minimum type size requirements specified in the ***Consumer Packaging and Labelling Regulations*** have been used as a guide to determining the legibility of mandatory information. Concern was expressed that legibility is not only affected by type size; additional factors such as type style and contrast also have an effect. Since the average life expectancy of the Canadian population is increasing, there will be a growing need for a more appropriate assessment of legibility.
APPROACH	Methods used by other regulatory agencies for assessing clarity and prominence will be assessed. The impact on consumer protection and information, the potential health and safety risk, the impact on trade and competitiveness, the cost and methods of enforcement and alternative options will also be examined.
CONSULTATION	Industry and consumer associations, government agencies, label designers, medical and scientific authorities.
IMPACT	Increased consumer protection since mandatory product information would be more visible; the packaging and food industries would have more flexibility in the choice of printing formats and presentation. Costs to industry should be minimized by a "phase-in" period for label changes.
DEPENDENCY	Coordination with all food labelling projects.

PROJECT: Ingredient Declarations on Food Labels		**COMPLEXITY:** 2 to 5
START DATE: November 1994		**PRE-PUBLICATION:** April 1997
PROJECT LEADERS:		**RECOMMENDATIONS:** (See Volume 2, p.3-3)
Pat Steele **Tel**: 613-952-8000(3800) **Fax**: 613- 952-7387	Ian Campbell **Tel:** 613-952-8000(3799) **Fax**: 613- 952-7387	
Sub-project Leaders:		
(1) John Stanger **Tel:** 613-952-8000 (3794)	**Fax:** 613-952-7387	3.4,
(2) Fred Joyce **Tel:** 613-952-8000 (3787)	**Fax:** 613-952-7387	3.5, 3.6, 3.8, 3.23
(3) Marion Zarkadas **Tel:** 613-952-8000 (3793)	**Fax:** 613-952-7387	3.9
(4) Pat Steele **Tel:** 613-952-8000 (3800) **Fax:** 613-952-7387	Rhea Reevie **Tel:** 613-952-8000(3792) **Fax:** 613-952-7387	3.10, 3.11,3.12
(5) Sue Lee-Spiegelberg **Tel:** 613-952-8000 (3798)	**Fax:** 613-952-7387	3.13, (see also Processing Aids, p.4-10 and 3.29, p.3-4)
PROJECT TEAM: HC/HPB - Nutrition Research, Chemical Evaluation AAFC - Headquarters and Regional representatives, Dairy, Fruit and Vegetable Division, Agri-Food Safety and Strategies Division IC - Headquarters and Regional representatives Industry and Consumer representatives		**REGULATIONS:** B.01.003, B.01.008, B.01.008(2)(7)(8)(9)(10), B.01.009, B.01.010, B.12.002, B.14.016, B.14.031(f)(g)(gg), B.14.032(d)(xii)(xiv)(A)(B), Division 16

OBJECTIVE	To determine which foods should carry labelling/ingredient information and to develop a labelling scheme that balances the need to provide consumers with essential information about the ingredients in foods with the need to control associated costs to the food industry. **Mandatory Labelling Information/Ingredient Labelling** 1) Define "non-consumer/non-retail" package and consider exemption and/or flexibility in the manner of providing labelling/ingredient information (3.4). 2) (i) Determine whether non-prepackaged foods/bulk foods, and certain other prepackaged products such as one bite confections and single portion foods sold in restaurants should carry labelling/ingredient information (3.6, 3.23)

OBJECTIVE (cont'd)	(ii) Development of criteria for ingredient exemptions and of alternative methods of providing information for those foods that are currently exempted. This includes products packaged at the retail level of trade and alcoholic beverages (3.5, 3.8) **Content of Ingredient List** 3) Development (based on health risk) of a priority list of allergens and other ingredients which give rise to anaphylactic shock or severe adverse food reactions (3.9). (4) (i) Examination of the common names of ingredients; determine whether specific names, functional names or class names are appropriate and whether the ingredient source should be indicated to identify the presence of an allergen and facilitate consumer understanding; consideration of other systems for identifying food additives (3.11, 3.12). (ii) Development of a basis for requiring the declaration of components and for the continued exemption of components in relation to a priority list of allergens (3.10). 5) Determining requirements for ingredient/component declaration of processing aids that do not carry through to the final product or that carry through in trivial amounts (3.13).
BACKGROUND	Prior to March 1, 1976, an ingredient list was not required on foods subject to a standard under the Act. At that time, ingredient lists became mandatory for all prepackaged foods with certain exceptions. This included standardized alcoholic beverages and vinegar. It was argued that an ingredient list should not be required on the latter since there is substantial transformation of the ingredients during fermentation and distillation. Under the ***Food and Drug Regulations***, there are several sections which deal with mandatory requirements for a label and ingredient list. Section B.01.008 exempts products packaged from bulk at retail from any ingredient listing. Section B.01.003 requires a label for all prepackaged products but exempts products such as one-bite confections from having a label. At the same time, this section stipulates a label on certain products that might not be prepackaged such as horse meat, and meat or poultry cooked on retail premises.

BACKGROUND (cont'd)	For products that are required to have an ingredient list, certain exemptions specific to its content also exist. For example, section B.01.009 exempts components of many ingredients from declaration. Examples include butter, flour and milk subject to compositional standards. Section B.01.010 permits certain ingredients to be declared by class names as in the example of most vegetable oils and milk ingredients where the source is not required to be shown. Many stakeholders asked that processing aids be defined and be exempted from ingredient labelling. There was also an interest in a more simplified means of food additive declaration such as the functional/numerical scheme used in Europe. A recent study of consumer use and understanding of nutrition information on food package labels conducted by the National Institute of Nutrition indicated that most Canadians are concerned about food labelling. Four out of five considered the list of ingredients important information in selecting foods. For those who did not use ingredient information, the key criticism was complexity and lack of clarity of the information. Both nationally and internationally, there is increasing concern about the presence of unidentified allergens in food. At the twenty-second meeting of the Codex Alimentarius Committee on Food Labelling held in Ottawa, April 26-30, 1993, the committee agreed that a re-examination of the Codex Alimentarius general labelling standard was needed. In 1989, HPB, the Canadian Restaurant and Food Services Association, the Allergy Information Association and the Canadian Society of Allergy and Clinical Immunology collaborated to develop a list of priority allergens, for the purposes of listing ingredients in the food service industry. Recently, a more restrictive list of hypersensitive agents associated most frequently with severe adverse reactions was issued by HPB for the purpose of cross-contamination precautionary labelling. A list of priority hypersensitive agents has not, however, been developed specifically for the list of ingredients on manufactured foods. It is expected that the existing information will facilitate its development.
APPROACH	Five project teams will be established to handle each of the five sub-objectives identified. The sub-projects will share a common approach and efforts will be integrated in order to increase efficiency, avoid duplication and overburdening the process of external consultation.

APPROACH (cont'd)	The proposals will include an ingredient identification scheme that might apply to all prepackaged foods, including those currently exempted. Consideration will also be given to unlabelled clerk served items. Research to be conducted on consumer understanding and needs in terms of labelling information will be considered (see Labelling Research, p. 3-7). In this study, the costs to industry, their ability to adequately respond, for example, to problems at the retail level, and other factors that would jeopardize the success of the endeavour or introduce unjustified costs will be determined. As with all regulatory projects the international implications of CUSTA, NAFTA and GATT agreements will be considered.
CONSULTATION	Consultation with industry groups, health professionals, allergy associations, consumer groups and other federal and provincial agencies with responsibility for food labelling.
IMPACT	Consumers, especially those with concerns about foods containing potential allergens would have better information with which to make appropriate food choices. More stringent ingredient labelling requirements at the retail level could result in additional labelling equipment cost. Additional employee training with software quality control procedures may also be required. At the manufacturing level, more stringent control procedures throughout the system are anticipated. The introduction of more analytical controls, involving critical ingredients would likely be necessary. Extra costs would ultimately be passed on to the consumer. The regulatory system would likely incur increased costs, in terms of increased inspection and analytical activity as well as research and evaluation support services.
DEPENDENCY	There are a number of sub-projects under the general umbrella of this project. The issue of whether retailers should apply ingredient labelling to foods that they package can proceed independently of the question of what the composition of an ingredient list should be. The question of group names is very dependent on the question of allergic responses to particular ingredients. Therefore, the same reasoning that would apply to possible component exemption will apply to whether group names are appropriate.

PROJECT: Date Marking	**COMPLEXITY:** 4
PROJECT LEADER: Diane Fournier **Tel:** 819-953-5641 **Fax:** 819-953-2931	**START DATE:** December 1994
PROJECT TEAM: AAFC, IC, HC - Microbial Hazards, DFO	**PRE-PUBLICATION:** August 1996
RECOMMENDATIONS: 3.14, 3.15, 3.16, 3.17 (3-14)	**REGULATIONS:** B.01.007(3)(c)(d), B.01.080(2)

OBJECTIVE	To review the issue of date marking on foods based on quality, health and safety considerations. The following recommendations were proposed in Phase 1 of the Regulatory Review process: 1. Amend paragraphs B.01.007(3)(c)(d) to revoke the durable life date exemptions for doughnuts and commissary items. 2. Review date marking with respect to products with modified atmosphere packaging. 3. Review the need for date marking on low acid foods packaged in hermetically sealed containers, and refrigerated products. 4. Support the use of "best before" dating on other products with a durable life of more than 90 days on a voluntary basis. 5. Consider extending the requirements under paragraph B.01.080(2) relating to the statement "previously frozen" to all products which have been frozen and thawed prior to sale.
BACKGROUND	Durable life dating regulations provide consumers with useful information regarding the freshness and potential shelf life of foods having a durable life of 90 days or less. The 1992 GPMC survey "Grocery Attitudes of Canadians" identified "freshness" and "best before dating" as a top labelling priority. There was considerable interest in the extension of date marking to all foods, for both "packed on" and "best before" dates. Similarly the revocation of certain exemptions was considered desirable. Since there is a misconception that products with modified atmosphere packaging are not subject to deterioration, it is considered appropriate to review date marking in that respect. Discussions are ongoing regarding the necessity for flexibility in the regulations that deal with the labelling of prepackaged meat products.

BACKGROUND (cont'd)	A modification to Division 27 is being considered to require a form of date marking based on a scientifically determined shelf life for low acid foods in hermetically sealed containers that are not commercially sterile and require refrigeration (see Regulation of Refrigerated Foods, p. 5-3). The Bureau of Microbial Hazards, Health Canada, is working towards the development of an industry code for refrigerated foods which may include a system for date marking. The labelling requirement dealing with " previously frozen" applies only to meat, poultry and fish and is intended to alert consumers that these products were previously frozen or made in part from frozen products and are not fresh in the traditional sense. This requirement should be extended to all foods that have been frozen and thawed prior to sale.
APPROACH	Except for the proposed revocation of certain exemptions under section B.01.007, these proposals involve health as well as fraud considerations and will be reviewed in cooperation with HC.
CONSULTATION	Food manufacturers, national and regional industry associations, health food and retail sectors, HC, other federal/provincial/municipal government departments and consumer groups and associations.
IMPACT	All sectors of the food industry will be affected. The extension of date marking requirements to more foods will increase associated labelling costs. Consumers will have more information required to make informed choices.
DEPENDENCY	Mutually dependent on Regulation of Refrigerated Foods, p. 5-3.

PROJECT: Common Name	**COMPLEXITY:** 4
PROJECT LEADER: Luisa Crapigna **Tel:** 613-952-8000(3791) **Fax:** 613- 952-7387	**START DATE:** April 1995
PROJECT TEAM: AAFC, HC/HPB - Nutrition Evaluation Division, DFO	**PRE-PUBLICATION:** November 1996
RECOMMENDATIONS: 3.18, 3.20 (3-102)	**REGULATIONS:** New regulations, B.01.006(1)

OBJECTIVE	To re-examine and harmonize among federal departments the use of qualifiers in conjunction with the common name and consider amending subsection B.01.006(1) to require that all words in the common name be of equal prominence.
BACKGROUND	The common name of standardized products may only be used on products that meet the standards of identity. Industry would like more flexibility in the use of modified common names to market products meeting changing lifestyle needs of consumers. This is administratively permitted provided an explanation is given on labels to identify all differences with standardized foods. The different approaches to this issue by federal departments is considered to be a problem and industry believes that inconsistencies must be minimized. The Consumer's Association of Canada supports the use of qualifiers in a well defined and prominent manner. Some stakeholders expressed the view that the qualifier should have identical prominence to that of the common name to assist consumers in distinguishing between "real" and "imitation" foods. In the U.S. a new rule under the ***Nutrition Labelling and Education Act*** provides for nutrient content claims describing a deviation from the standard to be used in conjunction with traditional standardized names.
APPROACH	Review of qualified common names and prominence of the common name to resolve different departmental approaches; review of comments in response to ***Consultation Document on Nutrition Labelling and Nutrient Content Claims*** issued December 9, 1993 by Health Canada and international initiatives including ***Codex Alimentarius*** requirements and proposed U.S. food standards (***Requirements for Foods Named by Use of a Nutrient Content Claim and a Standardized Term***, Federal Register, FDA, October 27, 1992). Regulatory and non-regulatory options will be considered.
CONSULTATION	Food industry manufacturers and retailers, national and regional industry associations, federal, provincial and international governments, health professionals and consumer associations.
IMPACT	Increased flexibility for industry to market new products in response to consumer demand. Increased costs to industry could be minimized by a "phase-in" period.
DEPENDENCY	Mutually dependant on Legibility of Mandatory Information p. 3-10.

PROJECT: Miscellaneous Mandatory Labelling Requirements	**COMPLEXITY**: 3
PROJECT LEADER: Rhea Reevie, **Tel:** 613-952-8000 (3792) **Fax:** 613- 952-7387	**START DATE:** January 1996
PROJECT TEAM: AAFC, IC, HC	**PRE-PUBLICATION**: July 1997
RECOMMENDATIONS: 3.24 (3.112)	**REGULATIONS:** B.11.204 (jam), B.14.009 (enzymes), B.19.002 and B.19.009 (vinegar)

OBJECTIVE	To re-examine the requirements to declare: "added pectin" on apple or rhubarb (naming the fruit) jam, "tenderized with enzymes" on meat, "percent acetic acid" on vinegar, and "for manufacturing use only" on certain vinegar and amend as required.
BACKGROUND	At the time of promulgation, these mandatory label declarations were considered necessary in order to respond to consumer expectations and were intended to alert consumers to the fact that the nature of the product differed in a specific way from the normal food. Today, the merit of this principle is open to question in view of the great variety of different products available on the market and the fact that more extensive ingredient listings are required than in the past.
APPROACH	No consensus of opinion has been achieved as to the validity of these regulations. They will be re-evaluated for relevancy in today's marketplace, clarity and consistency of approach with strong consideration of revocation.
CONSULTATION	Food industry manufacturers, national and regional industry associations, federal, provincial and municipal government departments, consumers' associations and import/export associations.
IMPACT	Clarification of labelling requirements for the domestic and imported processed fruit sector, the meat sector, vinegar producers and importers, other government departments, and consumers. Revocation of any of these requirements would be de-regulatory in nature and would not impose an additional burden to industry, consumers or government. Labels would be revised at industry's convenience.
DEPENDENCY	Independent

PROJECT: Country of Origin	**COMPLEXITY**: 5
PROJECT LEADER: Rhea Reevie **Tel:** 613-952-8000(3792) **Fax:** 613-952-7387	**START DATE:** May 1995
PROJECT TEAM: AAFC, IC, HC - HPB/BFRIIA	**PRE-PUBLICATION**: November 1996
RECOMMENDATIONS: 3.24 (3-112)	**REGULATIONS:** B.02.060 (old B.02.053, prior to Schedule 757), B.02.108

OBJECTIVE	Re-examine current country of origin requirements for brandy and wine and amend as required.
BACKGROUND	These regulations were promulgated in 1954 and 1963 respectively. Historically they have proven extremely difficult to enforce as there is no analytical method available to determine the validity of the declarations. The country of origin requirements for wine have been the subject of extensive consultation in the 1980's. Consumer and Corporate Affairs Canada initiated formal consultation in 1986 with all interested parties via ***Communiqué 47*** and informal consultation with the provinces in 1989. No consensus on the subject was reached. Several provinces have country of origin labelling requirements for food commodities. During Phase 1 of the Regulatory Review process concern was expressed by stakeholders with regard to the inconsistencies in the requirements for country of origin claims, not specifically for wine and brandy, but for all foods.
APPROACH	These regulations will be reviewed for relevancy, clarity and consistency with other regulatory requirements, both national and international, with strong consideration to be given to revocation if found to be obsolete.
CONSULTATION	Wine industry, distilled spirit industry, grape growers, consumers groups, federal and provincial government departments, international import/export associations
IMPACT	Revocation of these requirements would be deregulatory in nature and will not impose additional burden to industry, consumers and government. If revised, changes to the criteria to determine country of origin for wine and brandy and how these products should be labelled may result. A sufficient time frame will be provided for label revisions, so as not to increase costs to industry. Enforcement costs may decrease, if the requirements of the regulation are clarified.
DEPENDENCY	Independent

PROJECT: Miscellaneous Optional Labelling Requirements	**COMPLEXITY:** 3-5
PROJECT LEADER: Rhea Reevie, **Tel:** 613-952-8000 (3792) **Fax:** 613- 952-7387	**START DATE:** January 1996
PROJECT TEAM: AAFC, Foreign Affairs, Revenue Canada, IC	**PRE-PUBLICATION:** July 1997
RECOMMENDATIONS: 3.26, 3.27-28, (3-123)	**REGULATIONS:** B.01.072, B.02.034, Division 8 (smoked), B.19.008

OBJECTIVE	Re-examine requirements for optional label declarations such as the use of "smoked" on food products, the declaration of all varieties of vinegar present in blended vinegar when a claim is made, and to revoke the requirement for Caribbean rum.
BACKGROUND	These regulations guarantee that the information available to consumers is based upon uniform requirements and product claims are not misleading. During Phase 1 of the Regulatory Review, there was general agreement among the stakeholders that the regulations should be reassessed for inconsistencies, identification of obsolete regulations and that consideration should be given to developing guidelines to replace regulations wherever possible, except for nutritional claims. The majority of optional claims are controlled by guidelines. After promulgation of section B.02.034 in 1989, the Standing Joint Committee for the Scrutiny of Regulations questioned whether authority existed under the *Food and Drugs Act* to put in place a regulation to facilitate the marketing of Commonwealth Caribbean rum in Canada.
APPROACH	The regulations dealing with "smoked" on various cheeses and section B.01.072 will be reviewed with the aim to redraft for consistency. Section B.02.034 cannot be revoked until consultations are finalized with National Revenue and Foreign Affairs regarding required amendments to the *Importation of Intoxicating Liquors Act*.
CONSULTATION	The distilled alcoholic beverage industry, vinegar producers and importers, all other sectors of the food industry, federal and provincial government departments and consumers.
IMPACT	Revocation of any of these requirements would be de-regulatory in nature and would not impose any additional burden to industry, consumers or government. Labels would be revised at industry's convenience. Government may see some cost savings for enforcement.
DEPENDENCY	Independent

TEAM 4

COMPOSITIONAL STANDARDS, ADDITIVES, AND NUTRIENT ADDITION

Three categories of regulations were reviewed by Team 4: food additives, food standards and nutrition. Ten issues papers were developed and the subsequent discussions resulted in twenty-nine recommendations which are addressed below. Recommendations 4.1, 4.3, 4.11 and 4.24 (see the list on p. 4-3) indicate strategic directions which could have major effects on the responsiveness of the Regulatory Process and harmonization of requirements for domestic and imported products.

4.1 REGULATIONS THAT WERE RECOMMENDED FOR RETENTION

The following recommendations were reviewed and the affected regulations will be retained in the ***Food and Drug Regulations***:

B.01.044 **B.01.045**	Food additive limits and standards defined (4.9)[11]
D.03.002	Fortification - listing vitamins which may be added to categories of food (4.20)
D.03.003	Exemption for Foods for Special Dietary Use (4.23)
Part D	Schedule K , which is used as the basis of protein claims (4.27)

4.2 RECOMMENDATIONS THAT HAVE BEEN REJECTED

The following recommendation has been rejected:

Gelatin (4.8)

The proposal was to revoke the standard for gelatin (B.14.062) and use the Food Chemicals Codex (F.C.C.) standard for its composition. The F.C.C. does not contain a standard for gelatin, thus this regulation will be retained.

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[11] Recommendation number from Chapter 5, *Volume 1*, of *A Strategic Direction for Change*, HPB, 1993.

4.3 RECOMMENDATIONS THAT HAVE BEEN REVIEWED AND ACTION COMPLETED

Use of Subsection 4(d) of the *Food and Drugs Act* as Authority for the Food Additive Tables (4.10)

Food additives are added to food to accomplish a technical function and are considered to be safe over a lifetime of consumption in food. They are considered to be a special class of food ingredient and not adulterants. The current and appropriate authority for regulating food additives is given to the Governor-in-Council by subparagraph 30(1)(b)(iii) "conditions of sale" or (iv) "use of any substance as an ingredient". Division 16 of the Regulations was introduced in 1964 as a pre-market evaluation mechanism and is consistent with similar systems used in most industrialized countries. Therefore, no further action is contemplated with respect to this recommendation.

4.4 RECOMMENDATIONS ALREADY IN THE REGULATORY PROCESS

The recommendations listed below are currently being addressed in the regulatory process. They will not be addressed further within the Regulatory Review framework.

Transfer Nutrient Content Claims from Division 24 to Division 1 (4.12)

Nutrition labelling and claims were specifically excluded from the Regulatory Review, as they are being considered under another initiative (*Volume 1*, p.3). Therefore, this issue will not be addressed further under the Regulatory Review framework. Consultation on this issue is ongoing as part of the review of nutrition labelling and claims as addressed in: ***Consultation Document on Nutrition Labelling and Nutrient Content Claims*** issued on December 9, 1993.

To Revise Regulations Concerning Chemical Contaminants in Water & Ice (4.29)

This initiative is being addressed by Schedule 857 (currently in Step 1). It was announced in the ***Federal Regulatory Plan 1995*** as HCan/95-23-O-I Bottled Water (p. 87).

Foods for use in Weight Reduction Diets/ Maintenance of Healthy Weights (4.16)

This initiative was announced in the ***Federal Regulatory Plan 1995*** as HCan/95-20-O-I Foods for Use in Weight Reduction Diets (p. 86) (Schedule 897, currently in Step 2).

4.5 REGULATIONS RECOMMENDED FOR REVOCATION

The following regulations may be revoked, following consultation:

B.01.053	Instant or Ready Breakfast (4.23) It is proposed that this regulation be revoked and that products designated as instant or ready breakfasts or by other similar terms be required to comply with the compositional and labelling requirements for meal replacements as set out under Division 24 of the Regulations.
B.09.012	The standard for Mono- & Diglycerides (4.8)
B.16.004	Prohibition of Combinations of Class II Preservatives (4.5)

4.6 RECOMMENDATIONS FOR REGULATORY AMENDMENT

The projects described in this section are those which propose substantial changes to the Regulations and will require significant review and consultation. These changes are based on the possibility of regulating "differently" in order to provide increased flexibility to industry resulting in enhanced competitiveness while maintaining health and safety and quality and honesty in the marketplace. The project descriptions for these activities are contained in Annex 1.

- Food Additive Tables and GMP Listings (4.1, 4.2)
- Food Colours (4.4)
- Flavour Enhancers (4.7)
- Duplicate Food Standards (4.11)
- Processing Aids and Enzymes (3.13, 4.6, 4.7)
- Balanced Nutritional Food Supplements (4.13)
- Formulated Liquid Diets (4.14, 4.15)
- Infant Formula for Special Dietary Needs (4.17)
- Experimental Infant Formula (4.18)
- Enrichment of Rice and of Cornmeal, Flour and Grits (4.25)
- Nutrient Addition - General Provisions (4.26)
- Substitute Food - Fortified Vegetarian Soy Beverage (4.28)

In addition, the following projects will result in changes to the Regulations that are of a more routine nature. The amendments proposed below will increase the usefulness of regulation for manufacturers, industry advisors and regulators by increasing clarity, consistency and decreasing overlap.

Combine Divisions 14 Meat and Meat Products and 22 Poultry and Poultry Products[12]

Many regulations apply equally to both commodities. Therefore, by combining these Divisions of the Regulations, significant duplication could be eliminated. If a consensus is achieved on the usefulness of this suggestion, a regulatory amendment will be drafted for pre-publication in ***Canada Gazette Part I***.

Imported Infant Formulas (4.19)

This recommendation proposed an amendment to sections B.24.017, B.25.046, B.25.048 and B.25.060 to clarify that requirements are applicable to "importers" as well as manufacturers. Although the definition of "manufacturer" under Part A of the Regulations was considered to include importers at the time the above regulations were drafted, it appears that this is not readily apparent. Amendments will be drafted to clarify the intent of the regulation by adding the word "importer" wherever the word "manufacturer" is used.

Consistency of Nutrient Restoration and Fortification Regulations (4.21)

The Regulations which set out minimum and maximum requirements for vitamins and mineral nutrients in foods will be examined to ensure clarity and consistency in the meaning of the maximum levels.

Modify the Table to D.03.002 (Nutrient Addition) (4.22)

The current regulation refers to many commodities to which nutrients may be added, but gives no indication to which section of the Regulations it refers. Referencing each item in the Table to section D.03.002 would be useful in the administration of the Regulations and for compliance purposes. A method of providing this reference information will be investigated.

4.7 RECOMMENDATIONS FOR POLICY DEVELOPMENT

The following project is described in Annex 2:

- Micro-Nutrient Addition to Foods will address:
  - Nutrient Restoration (4.24)
  - Restoration of Nutrients to Reduced-Fat Dairy Products (4.25)
  - Substitute Foods - General (4.28)

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[12] This was an internal recommendation (see *Volume 2*, p. 4-67).

ANNEX 1

PROJECT DESCRIPTIONS FOR REGULATORY AMENDMENTS

COMPOSITIONAL STANDARDS, ADDITIVES AND NUTRIENT ADDITION

PROJECT: Food Additive Tables & GMP Listings	**COMPLEXITY:** 5
PROJECT LEADER: Bruce Lauer **Tel:** 613-957-1696 **Fax:** 613-990-1543	**START DATE:** May 1994
PROJECT TEAM: Bureau of Chemical Safety	**PRE-PUBLICATION:** January 1997
RECOMMENDATIONS: 1.9 (1-4), 4.1, 4.2 (4-28)	**REGULATIONS:** Division 16

OBJECTIVE	4.1 To consider the establishment of a separate positive list for food additives having an unlimited ADI (acceptable daily intake) that are now regulated at levels consistent with GMP (good manufacturing practice). 4.2 To investigate the consolidation of other food additives into a table of listings arranged in alphabetical order, in which regulation of the allowable areas of use of each additive is by food class.
BACKGROUND	It has been observed that the Food Additive Tables may be too restrictive and place inordinate emphasis on the legal definitions of "standardized" and "unstandardized" products. This results in inequities in the listings whereby an additive conceivably might be allowed in a standardized food product, but not in its unstandardized analog (or *vice versa*), even though the two foods may belong in the same class of food stuffs and equally require use of the additive. A regulatory system for food additives based on food classes or categories is envisaged. Such systems are in use in Sweden, Denmark and the Netherlands.
APPROACH	The food additive tables will be reviewed to identify those additives with unlimited ADI's and to reorganize the tables to identify those substances in a separate listing. The remaining additives will then be reorganized according to use in food classes.
CONSULTATION	All major trade associations, AAFC (Food Division), provincial governments and consumers associations
IMPACT	Completion of this activity will curtail the need for "minor use" submissions thereby resulting in cost savings to government and industry. It will also help to clarify the food additive tables by shifting their focus from standardized and unstandardized foods to one based on food classes. There should not be any costs to consumers or industry in re-drafting the food additive tables. Enforcement costs should remain the same.
DEPENDENCY	Coordinate with Processing Aids and Enzymes, p. 4-10 and Rationalization/Harmonization of Non-Health Related Food Standards, p. 1-9.

PROJECT: Food Colours	**COMPLEXITY:** 4
PROJECT LEADER: Frank Lancaster **Tel:** 613-957-0980 **Fax:** 613-941-4775	**START DATE:** January 1994
PROJECT TEAM: Jim Lawrence, Dennis Lein	**PRE-PUBLICATION:** June 1995
RECOMMENDATIONS: 4.4 (4-55)	**REGULATIONS:** Division 6

OBJECTIVE	1. To consider whether the current food colour certification program and related specifications should remain, be replaced, or be eliminated. 2. To determine whether FCC specifications for synthetic food colours could replace, where possible, current regulations. 3. To consider adopting international specifications for natural colours.
BACKGROUND	Synthetic food colours are imported into Canada from several countries. At present, the USA is the only other country which has a certification program, but other countries are currently moving in that direction. Division 6 of the ***Food and Drug Regulations*** and Table 3 of Division 16 identify the colorants that may be used in food and their maximum limits of use. There is a requirement for the certification of all synthetic food colours, and monitoring is conducted in order to ensure that only colours of suitable purity reach the Canadian food supply. Because of their distinctive nature, food colours are the only additives which are required to undergo such certification. It was suggested that, where possible, the current regulations for food colours could be replaced by specifications for colours described in ***Food Chemicals Codex*** or the ***JECFA Compendium of Food Additive Specifications***.
APPROACH	A questionnaire, covering the queries and concerns raised during the first part of the Review, was prepared and distributed for comment. Suggestions regarding how the program could be improved were also solicited. A report is now being prepared which will address the need for regulations and certification, and the possible referencing of international specifications.
CONSULTATION	Consultation with major colour manufacturers, Canadian importers, and industry associations is complete.
IMPACT	The certification program currently prevents food colours with unsuitable levels of impurities from entering the food supply, and provides Branch and customs staff with a clear process for monitoring these substances. It ensures that all suppliers to Canada must meet equal standards of product quality. Certification costs are currently borne by the Canadian government.
DEPENDENCY	Independent

PROJECT: Flavour Enhancers	**COMPLEXITY:** 3
PROJECT LEADER: Dennis Lein **Tel:** 613-957-1701 **Fax:** 613-990-1543	**START DATE:** January, 1994
PROJECT TEAM: Bruce Lauer, John Salminen, AAFC (Food Division)	**PRE-PUBLICATION:** May 1995
RECOMMENDATIONS: 4.7	**REGULATIONS:** New regulation

OBJECTIVE	To investigate the regulatory control of flavour enhancers, internationally, with a view to developing a suitable means to regulate and define these substances under the ***Food and Drug Regulations***.
BACKGROUND	Under the current regulations the term "flavour enhancer" is not defined and the use of these substances is not specifically controlled. It has been suggested that an approved list of flavour enhancers would clearly identify those substances that could have this use.
APPROACH	To review and evaluate the options in addressing this issue and to explore potential definitions for "flavour enhancer". The second phase would be to consider referencing the desired approach in the Regulations.
CONSULTATION	Development of a Departmental position, followed by consultation with other government departments, provincial governments, industry associations and consumers.
IMPACT	A clear indication of what substances may be used as flavour enhancers.
DEPENDENCY	Independent

PROJECT: Duplicate Food Standards	**COMPLEXITY**: 4
PROJECT LEADER: Greg Borotsik **Tel:** 613-957-0189 **Fax:** 613-941-3537	**START DATE:** January 1995
PROJECT TEAM: BFRIIA, AAFC, DFO	**PRE-PUBLICATION:** June 1996
RECOMMENDATIONS: 4.11 (4-59)	**REGULATIONS:** Standards TBA

OBJECTIVE	To identify non-health related food standards in the ***Food and Drug Regulations*** which are also found in other federal regulations.
BACKGROUND	Food standards were created to provide an identity for products trading under established names and to provide a standard against which to measure adulteration. Prior to 1968, HC was responsible for the development and enforcement of product standards. Since that time, responsibility for the non-health related aspects of standards was assumed by CCAC, AAFC, and DFO. Under the ***Canada Agricultural Products (CAP) Act***, AAFC has established identity and compositional standards which are used to control interprovincial trade in agricultural products. Parallel situations exist in the ***Meat Inspection Regulations*** and the ***Fish Inspection Regulations*** and many of the standards contained in these regulations are similar to those contained in the ***Food and Drug Regulations***. In addition, the standards in the CAP regulations, ***Fish Inspection Regulations***, ***Meat Inspection Regulations*** and ***Food and Drug Regulations*** are under the same constitutional authority, and their coverage is now identical.
APPROACH	Identify non-health related food standards in federal regulations and evaluate the impact of removing them from the ***Food and Drug Regulations***.
CONSULTATION	Other federal departments, the provinces, industry associations and consumers.
IMPACT	There should be no cost to the stakeholders as the standards will remain within the federal government purview.
DEPENDENCY	Coordinate with Rationalization/Harmonization of Food Standards, p. 1-9.

PROJECT: Processing Aids and Enzymes	**COMPLEXITY:** 5
PROJECT LEADER: Bruce Lauer **Tel:** 613-957-1696 **Fax:** 613-990-1543	**START DATE:** July 1994
PROJECT TEAM: Bureau of Chemical Safety, AAFC (Food Division)	**PRE-PUBLICATION:** January 1997
RECOMMENDATIONS: 3.13 (3-35), 4.6, 4.7 (4-37)	**REGULATIONS:** Division 16

OBJECTIVE	3.13 To consider the establishment of a definition for a "processing aid" that would distinguish it from a food additive. 4.6 To consider the de-listing of and regulation by other means, of processing aids, including some enzymes to which there is little human exposure. 4.7 To investigate the possibility of referencing the Codex Alimentarius lists of processing aids.
BACKGROUND	Processing aids are substances such as those used in food processing that do not appear in the final product. The food industry has indicated that listing or referencing processing aids would be useful in that the manufacturer would no longer have to search to determine which substances were acceptable for this use. It was also indicated that the term "processing aid" should be defined, categorized and, where possible, reference made to internationally accepted lists.
APPROACH	A definition for processing aid will be developed and food additives reviewed to identify which of these are processing aids. Alternatives to listing these substances in the Canadian regulations would be proposed for consultation.
CONSULTATION	Other government departments, industry, consumer organizations and international agencies.
IMPACT	This project will define more precisely those materials that are processing aids and may provide for their exemption from the notification requirements for food additives. It may also allow petitioners to better ascertain regulatory requirements for such products. This project will also permit better identification of those substances that should be exempt from labelling requirements.
DEPENDENCY	Coordinate with the projects concerning Ingredient Declaration of Food Labels, p. 3-11 and Food Additive Tables and GMP Listings, p. 4-6.

PROJECT: Nutritional Food Supplements	**COMPLEXITY:** 4
PROJECT LEADER: Christina Zehaluk **Tel:** 613-957-1739 **Fax:** 613-941-6636	**START DATE:** January 1994
PROJECT TEAM: Nora Lee and Margaret Cheney	**PRE-PUBLICATION:** April 1995
RECOMMENDATIONS: 4.13 (4-104)	**REGULATIONS:** B.24.100 - B.24.103

OBJECTIVE	To amend the ***Food and Drug Regulations*** to make provision for balanced formulated foods to be used as supplements containing appropriate macro and micro-nutrients.
BACKGROUND	There is no provision under the current regulations for the advertising and sale of balanced nutritional supplements. Formulated liquid diets are intended for use under medical supervision and meal replacements are intended to replace entire meals. However, there are products manufactured and sold in compliance with the regulations for formulated liquid diets which could benefit the general public, but cannot be advertised as such. There are instances where adults and children who are not under medical supervision would benefit from nutrient supplementation of their diets. The elderly population who could benefit from dietary supplementation is growing and should have ready access to these products. Manufacturers of suitable products should be allowed to advertise them directly to the intended consumer.
APPROACH	Regulatory control of the composition of balanced nutritional supplements is proposed to ensure that product composition is consistent with good dietary practices and the ***Nutrition Recommendations***. Regulatory proposals for balanced nutritional food supplements will be prepared for publication in ***Canada Gazette Part I***.
CONSULTATION	Manufacturers of formulated liquid diets and meal replacements, other food industry/health professional/consumer associations, provincial governments. Consideration will be given to relevant international and U.S. guidelines and regulations.
IMPACT	Consumers would have increased choice of specific nutritional supplements as foods. The proposed amendment would accommodate industry innovation based on accepted dietary practice and in response to changing demographics and lifestyles.
DEPENDENCY	Independent

PROJECT: Formulated Liquid Diets ("Medical Foods")	**CATEGORY:** 4
PROJECT LEADER: Christina Zehaluk **Tel:** 613-957-1739 **Fax:** 613-941-6636	**START DATE:** July 1, 1994
PROJECT TEAM: Margaret Cheney and Nathan Aboagye	**PRE-PUBLICATION:** October 1995
RECOMMENDATIONS: 4.14 and 4.15 (4-105)	**REGULATIONS:** B.24.001, B.24.100 to B.24.103

OBJECTIVE	To amend the ***Food and Drug Regulations*** to provide for the sale of foods for special medical purposes (FSMP) also known as "medical foods".
BACKGROUND	The current category of formulated liquid diets covers a very wide range of products, from balanced nutritional supplements to products which have been designed for the dietary management of very specific medical conditions. The response to recommendation 4.13 deals with the former. This project description deals with recommendations 4.14 and 4.15 since it has been decided to deal with FSMP and experimental new formulated liquid diets together. Pre-market notification will allow the regulatory agency to decide whether the distribution of FSMP need to be restricted. Status quo is not considered an acceptable alternative since both science and dietary/medical practice have evolved since the current regulations were promulgated.
APPROACH	A background document and proposals for regulatory amendments defining and setting out requirements for FSMP will be prepared for external consultation. Comments received will be considered in drafting proposed amendments to the ***Food and Drug Regulations*** for publication in the ***Canada Gazette Part I***.
CONSULTATION	Drugs Directorate (to ensure no overlaps), manufacturers of formulated liquid diets, other food industry associations and health professional associations.
IMPACT	The proposed amendment would accommodate industry innovation based on new scientific developments and accepted dietary/medical practice. Consumers and health professionals would have faster access to new products.
DEPENDENCY	Independent

PROJECT: Infant Formula for Special Dietary Use	**COMPLEXITY:** 4
PROJECT LEADER: Nathan Aboagye **Tel:** 613-957-1733 **Fax:** 613-941-6636	**START DATE:** May 1, 1994
PROJECT TEAM: Christina Zehaluk, Margaret Cheney	**PRE-PUBLICATION:** December 1995
RECOMMENDATIONS: 4.17 (4-111)	**REGULATIONS:** Division 25

OBJECTIVE	To amend Division 25 of the ***Food and Drug Regulations*** to make provision for the sale of formulas for infants with special dietary needs.
BACKGROUND	The compositional requirements for infant formula are intended to apply to formulas for normal term infants. Specific exemptions for formulas for special dietary use now require regulatory amendment for each deviation from the compositional requirements. This impedes the provision of formulas to infants with special dietary needs.
APPROACH	Manufacturers, importers or distributors of infant formulas for special dietary use would be required to justify the composition of their non-compliant formula. The current pre-market notification system for infant formulas would also apply to these infant formulas.
CONSULTATION	Infant formula manufacturers, the Canadian Paediatric Society, health professionals.
IMPACT	Manufacturers will have more flexibility in the manufacture of innovative products for infants' special dietary needs. Health professionals and consumers will have quicker access to a wider range of products and the regulatory system will be more efficient and responsive to scientific and technical progress in the field of infant nutrition.
DEPENDENCY	Coordinate with Experimental Infant Formulas, p. 4-14.

PROJECT: Experimental Infant Foods	**COMPLEXITY:** 4
PROJECT LEADER: Nathan Aboagye **Tel:** 613-957-1733 **Fax:** 613-941-6636	**START DATE:** May 1, 1994
PROJECT TEAM: Christina Zehaluk, Margaret Cheney	**PRE-PUBLICATION:** December 1995
RECOMMENDATIONS: 4.18 (4-111)	**REGULATIONS:** Division 25

OBJECTIVE	To amend Division 25 of the ***Food and Drug Regulations*** to make provision for new experimental foods for infants and young children.
BACKGROUND	Some experimental new foods for infants and young children may not comply with the Regulations in terms of composition and/or may contain ingredients which have not previously been used in such foods. Yet, they may be required for the dietary management of certain conditions/ physiological states or may be formulated in response to new scientific or technical progress in paediatric nutrition. There is no provision under Division 25 for the sale of such foods, and they are currently being sold under Letters of Temporary Marketing Authorization (TMA). A separate TMA must be issued for every new situation in which a physician prescribes an experimental new food for a patient and this imposes unnecessary burdens on the physician, the industry and the regulatory agency.
APPROACH	These products would be subject to the same type of pre-market notification currently required for infant formulas and conditions of sale may be imposed. However, a new regulation which provides for the use of a new food after evaluation in a variety of similar situations would lessen the burden on parties involved in such research.
CONSULTATION	Manufacturers of infant formula and infant foods.
IMPACT	Manufacturers will have more flexibility in the manufacture of innovative products for special dietary needs for infants and children, health professionals and consumers will have quicker access to a wider range of products and the regulatory system will be more efficient and responsive to scientific and technical progress in the field of infant nutrition.
DEPENDENCY	Coordinate with Infant Formulas for Special Dietary Needs, p. 4-13

PROJECT: Enrichment of Rice and of Cornmeal, Flour and Grits	**COMPLEXITY:** 4
PROJECT LEADER: Eric Driscoll **Tel:** 613-957-3841 **Fax:** 613-941-6636	**START DATE:** September 1, 1994
PROJECT TEAM: Nutrition Evaluation Division	**PRE-PUBLICATION:** April 1996
RECOMMENDATIONS: 4.25 (4-134)	**REGULATIONS:** New regulations under Division 13 and amendments to section D.03.002

OBJECTIVE	To make provision under the Regulations for the enrichment of rice and of corn meal, flour and grits.
BACKGROUND	Currently, the ***Food and Drug Regulations*** require the mandatory restoration of certain nutrients to flour. The enrichment of alimentary pastes (pasta), breakfast cereal and instant rice is voluntary. Rice and corn products are the only staple cereal grain products used in Canada for which provision for nutrient addition does not exist under the Regulations. Canadian demographics indicate a significant increase in the population who consume rice as a staple food, therefore, enrichment of white rice is a nutritionally valid strategy. Because of changing demographics and the increased use of ethnic foods, it is also proposed that provision be made under the Regulations for the optional enrichment of corn meal, flour and grits, which may be a dietary staple .
APPROACH	Proposals will be developed to permit the enrichment of white milled rice, and corn meal, corn flour and corn grits with B vitamins and iron in accordance with the enrichment permitted in the U.S. standards for these foods.
CONSULTATION	Canadian rice millers and importers, manufacturers and importers of corn products, health professionals and consumer representatives.
IMPACT	Canadian rice millers will be able to enrich their product and the importation of enriched white rice and of enriched corn products primarily from the United States would be allowed. Consumers would have the choice of purchasing enriched white rice and enriched corn products. This proposal recognizes the increasing cultural diversity of the Canadian population and changing dietary patterns and thus addresses the nutritional needs of those segments of the population who consume white rice or corn products as dietary staples.
DEPENDENCY	Independent

PROJECT: Nutrient Addition - General Provisions	**COMPLEXITY:** 4
PROJECT LEADER: Christina Zehaluk **Tel:** 613-957-1739 **Fax:** 613-941-6636	**START DATE:** January 1, 1995
PROJECT TEAM: Nutrition Evaluation Division	**PRE-PUBLICATION:** June 1996
RECOMMENDATIONS: 4.26 (4-134)	**REGULATIONS:** Part D (sections D.01.009, D.01.010, D.01.11, D.02.009, D.02.010 and D.02.11)

OBJECTIVE	To revoke the above sections of the ***Food and Drug Regulations*** and develop commodity-specific regulations for the addition of nutrients for certain food categories.
BACKGROUND	The above sections of the ***Food and Drug Regulations*** contain general provisions respecting levels of added vitamin and mineral nutrients in foods and are applicable to the following categories of foods: infant cereal products, substitutes for butter similar to margarine, flavoured beverage mixes and bases for addition to milk, instant breakfasts, various fruit and vegetable drinks and beverages and dehydrated potatoes. The levels for vitamins and mineral nutrients provided for in these sections are not commodity-specific and should be amended to reflect current government policies respecting nutrient addition to foods.
APPROACH	The general provisions in the above sections would be replaced with commodity-specific regulations for nutrient addition and will also be moved from Part D to the appropriate Division of Part B of the Regulations. These amendments would result in nutritionally superior products with new vitamin fortification levels which more accurately reflect current policy regarding nutrient fortification. Revocation of the instant breakfast regulation is indicated on p. 4-3.
CONSULTATION	Products other than instant breakfasts will require external consultation particularly in the case of infant cereal products. AAFC, provincial governments, pertinent segments of the food industry, health professionals and consumer groups.
IMPACT	Infant cereal products will be formulated to be of higher nutritional quality more closely resembling whole cereal grains. The industry would face the cost of reformulation where necessary but would benefit from the promotion of nutritionally superior products.
DEPENDENCY	Independent

PROJECT: Substitute Food - Fortified Vegetarian Soy Beverages	**COMPLEXITY:** 4
PROJECT LEADER: Eric Driscoll **Tel:** 613-957-3841 **Fax:** 613-941-6636	**START DATE:** July, 1994
PROJECT TEAM: Nutrition Evaluation Division	**PRE-PUBLICATION:** March 1996
RECOMMENDATIONS: 4.25 (4-134)	**REGULATIONS:** New regulations

OBJECTIVE	To provide for the advertising and sale of nutritionally adequate vegetarian soy beverages under the ***Food and Drug Regulations***
BACKGROUND	The Regulations provide for the advertising and sale of certain foods (e.g., simulated meat) which may be represented as substitutes for staple foods and HPB policy requires such products to be nutritionally equivalent to the staple foods replaced. Vegetarian beverages may be fortified in the United States. A B.C. report on imitation milk products recommended that the provincial and federal governments should allow the consumer the choice of high quality alternative dairy products. A subsequent follow-up study found that B.C. consumers strongly support the sale of imitation dairy products and feel that their choice should not be restricted. They also indicated that "substitutes" are "thought to have nutritional value and can be used in place of dairy products". The sale of nutritionally inferior vegetarian soy beverages represents a potential risk of nutritional deficiency to the consumer who wishes for dietary, health, cultural or religious reasons to consume vegetarian beverages as milk alternatives. A submission has been received to amend the ***Food and Drug Regulations*** to provide for the "nutritional fortification of non-dairy beverages".
APPROACH	Regulatory provision would be made for the addition of vitamins, mineral nutrients and amino acids to such products. Representation of these products in a manner which would best contribute to the protection of the health of the Canadian consumer would be investigated. Following broad consultation with stakeholders, regulatory amendments will be proposed.
CONSULTATION	AAFC, food industry, consumers, provincial governments, health professionals
IMPACT	This initiative will provide opportunities for innovation for the food industry in response to consumer demands and dietary patterns. The consumer would have available nutritionally safe vegetarian beverage alternatives.
DEPENDENCY	Independent

ANNEX 2

PROJECT DESCRIPTIONS FOR POLICY DEVELOPMENT INITIATIVES

COMPOSITIONAL STANDARDS, ADDITIVES AND NUTRIENT ADDITION

PROJECT: Micronutrient Addition to Foods	**COMPLEXITY:** 4
PROJECT LEADER: Margaret Cheney **Tel:** 613-957-0352 **Fax:** 613-941-6636	**START DATE:** September 1, 1994
PROJECT TEAM: TBA	**PRE-PUBLICATION:** January 1997
RECOMMENDATIONS: 4.24, 4.25, (4-134)	**REGULATIONS:** To be determined

OBJECTIVE	To review the current policy with respect to micronutrient addition to foods and make proposals for amendments to the ***Food and Drug Regulations*** as required.
BACKGROUND	The current policy with respect to the addition of vitamins and mineral nutrients to foods was outlined in TIL No. 351 published by the Department in 1971. The policy states that vitamin and mineral addition to foods is acceptable for the following reasons: to restore processing losses; to provide nutrient(s) to prevent or eliminate demonstrated deficiencies in the population or segments of it; and to ensure the nutritional quality of substitute foods and foods used as sole sources of nourishment. The Canadian policy with respect to micronutrient addition to foods is virtually identical to that of the U.S. FDA and that of the ***FAO/WHO Codex Alimentarius***. Addition of vitamins, mineral nutrients and amino acids to foods is controlled under the ***Food and Drug Regulations*** and is restricted to those nutrients and foods specifically provided for therein. A regulatory amendment is required each time there is a need to make provision for the addition of a nutrient to a food not listed in the Regulations.
APPROACH	It is proposed to strike a multi-sectoral expert advisory committee including representation from government, consumers, food industry, health professionals and academia, to review current policies with respect to the addition of micronutrients to foods. The committee will be established in line with the directive issued on April 12, 1994 in ***Information Letter No. 810 - Health Protection Branch Advisory Committees***. It is proposed that the committee will consider health, safety and trade issues related to the addition of micronutrients to foods and make recommendations.
CONSULTATION	See above
IMPACT	Addition of micronutrients to foods to meet the needs of Canadians and to enhance industry competitiveness.
DEPENDENCY	Independent

TEAM 5

MICROBIOLOGY

Team 5 reviewed all sections of the *Food and Drug Regulations* and pertinent guidelines concerning microbiological and extraneous material hazards in foods, drugs, cosmetics and medical devices. Ten issue papers were developed by Team 5; one dealt with drugs, cosmetics and medical devices only (Recommendation 5.2) and will not be discussed further within this review. The remaining nine issue papers resulted in nineteen recommendations which are addressed below. Particular note should be taken of the proposed use of performance standards for, and the recognition of equivalent processes to pasteurization, which should contribute to both harmonization of standards and responsiveness of the regulatory control mechanisms for the safety of dairy products.

5.1 REGULATIONS THAT WERE RECOMMENDED FOR RETENTION

The following regulations were reviewed by Team 5 and were recommended for retention.

B.04.010 **B.04.011**	Salmonella in chocolate and cocoa (5.1)[13]
B.08.014A	Salmonella in milk powder (5.1)
B.22.033	Salmonella in egg products (5.1)

5.2 RECOMMENDATIONS THAT HAVE BEEN REJECTED

The following regulation was recommended for modification but the recommendation has been rejected:

Mould in Tomato Products (5.13)

The tomato product regulations were originally developed under the ***Canada Agricultural Products (CAP) Act*** and designed as a way of assessing raw product quality. Sections B.11.016 and B.11.017 were derived from the CAP Act (tomato product) regulations and incorporated into the ***Food and Drug Regulations***. During the initial phases of the Regulatory Review, the jurisdictional issue of these regulations was not considered. The CAP Act governs international

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[13] Recommendation number from Chapter 5, *Volume 1* of *A Strategic Direction for Change*, HPB, 1993.

and interprovincial trade in agricultural food products including processed fruit and vegetable products. Sections B.11.016 and B.11.017 of the ***Food and Drug Regulations*** apply as conditions of sale at all levels of trade including intraprovincially. Therefore, these regulations will be retained and reviewed further

5.3 RECOMMENDATIONS THAT HAVE BEEN REVIEWED AND ACTION COMPLETED

None of the recommendations has been completed.

5.4 RECOMMENDATIONS ALREADY IN THE REGULATORY PROCESS

The recommendations addressed below are currently being processed in the Regulatory Process or are part of a larger Health Canada initiative. They will not be addressed further within the Regulatory Review framework.

Cheese made from Heat-Treated Milk (5.4)

This initiative is being addressed by Schedule 836 (currently in Step 2). It was announced in the ***Federal Regulatory Plan 1995*** as HCan/95-26-O-I Microbiological Standards for Cheese (p. 88). Pre-publication in *Canada Gazette Part I* is expected early in 1995.

Microbiological Standards for Water & Ice (5.6)

This initiative is being addressed by Schedule 857 (currently in Step 1). It was announced in the ***Federal Regulatory Plan 1995*** as HCan/95-23-O-I Bottled Water (p. 87).

5.5 REGULATIONS RECOMMENDED FOR REVOCATION

The following regulations may be revoked, following consultation:

B.08.007	Sterilized Milk (5.12)
B.08.024 **B.08.025**	Bacteria in Raw Milk for Manufacture (5.9) Transfer to AAFC or the provinces.
B.14.013 **B.14.014**	Meat in Hermetically-Sealed Container (5.14)

B.14.061 (b)(c)	Edible Bone Meal & Flour (5.15) (microbiological standard)
B.14.062(d)	Gelatin (5.15) (microbiological standard)
B.14.072	Cooked Meat Storage (5.10) (BBQ, roasted, broiled for sale at retail) Transfer to the provinces.
B.21.027 (c)(ii)(iii)	Fish Protein (5.15) (microbiological standard)
B.22.026	Cooked Poultry Storage (5.10) (BBQ, roasted, broiled for sale at retail) Transfer to Provinces.

5.6 RECOMMENDATIONS FOR REGULATORY AMENDMENT

The projects identified in this section propose substantial changes to the Regulations and will require significant review and consultation. They are based on the principle of regulating "differently" in order to provide increased flexibility to industry and to enhance competitiveness while maintaining health and safety and quality and honesty in the marketplace. Project descriptions for the following recommendations are contained in the Annex to this chapter:

- Pasteurization (5.3, 5.4)
- Dairy Microbiological Standards (5.5)
- Smoked Fish (5.7)
- Salmonella in Frog's Legs (5.11)
- Microbiological Methods (5.19)

5.7 RECOMMENDATIONS FOR POLICY DEVELOPMENT

Develop and Monitor an Industry Code for Refrigerated Foods (5.16)

The Codex Alimentarius draft document on this issue will be reviewed by HPB and used as a basis for consultation leading to a Canadian industry code for these products. Any regulatory issues arising from this review will be discussed with stakeholders. Project Leader: Ms. Hélène Couture, Bureau of Microbial Hazards, Tel: 613-957-1742, Fax: 613-952-6400.

Review of Microbiological Guidelines (5.17)

Microbiological Guidelines address issues of health and safety, adherence to good manufacturing practices, food quality and provide for the control of potential health hazards for some foods for which there are no microbiological standards. They also provide a non-regulatory alternative for the control of hazards from certain foods. The Microbiological Guidelines will be reviewed and compared with to those published by other agencies, such as the International Commission on Microbiological Specifications for Foods of the International Association of Microbiological Societies, the Codex Alimentarius Commission, the International Dairy Federation, etc. and harmonized as required. Project Leader: Dr. Karen Dodds, Chief, Evaluation Division, Bureau of Microbial Hazards, Tel: 613-957-0884, Fax: 613-952-6400.

Extraneous Material Guidelines (5.18)

There are 28 guidelines for extraneous material in foods that cover a wide variety of extraneous material types. These guidelines are used to interpret and provide enforcement guidance regarding Sections 4 and 7 of the Act. There is a need to review, and if possible, harmonize these guidelines with guidelines from other countries. Import control and the potential development of MOUs are also being considered under the Import Control project, p. 1-3. Project Leader: Bruce Bowen, Evaluation Division, Bureau of Microbial Hazards, Tel: 613-957-1745, Fax: 613-952-6400.

Amend the Regulations Concerning Low Acid Food in Hermetically Sealed Containers (5.8)

The Canadian industry has maintained that requirements for domestic and imported products should be identical in that importers should be required to provide processing information about imported products. This has been a long standing complaint of domestic manufacturers. Importers may have an unfair economic advantage because the costs of quality control to ensure product safety may be substantially less for domestic manufacturers.

Shelf-stable LAFHSC could be monitored more closely if Division 27 was revised to state that importers are responsible to obtain and provide processing information about products they import. The approach used by the Department of Fisheries and Oceans should be considered: 1) Evaluate the safety of new products coming into Canada, 2) Establish a list of accredited importers and countries, 3) Send qualified personnel overseas in order to establish proper quality control. The recommendation to institute tighter controls over imported products will be investigated as part of the Import Control project, p. 1-3. Project Leader: Mr. Paul Mayers, Bureau of Microbial Hazards, Tel: 613-952-5137; Fax: 613-952-6400.

Modify Microbiological Methods (5.19)

Food microbiological standards established in the Regulations are verified through microbiological analyses according to HPB Official Methods. For certain foods, guidelines are used in place of regulatory standards, and methods exist to support these guidelines. Microbiological methods are developed and evaluated in the Food Directorate and are published in the Compendium of Analytical Methods. These methods are widely distributed and used by industry and government laboratories. Currently, Official Methods are microorganism and food specific and do not allow for the inclusion of equivalent analytical methods. Official Methods will be revised to be microorganism specific and published in The Compendium of Analytical Methods. When more than one method of analysis is equivalent, all methods will be included. Consultation with AAFC, DFO, provincial governments and private laboratories will be conducted. The use of common methods facilitates increased harmonization within HPB, AAFC, DFO and the food industry. An increased choice of equivalent alternative methods for industry and regulatory agencies will allow more flexibility and the use of new technology. Also, accreditation of laboratories will be facilitated. Project Leader: Dr. Karen Dodds, Bureau of Microbial Hazards, Tel: 613-957-0884, Fax: 613-952-6400.

ANNEX

PROJECT DESCRIPTIONS FOR REGULATORY AMENDMENTS

MICROBIOLOGY

PROJECT: Pasteurization	**COMPLEXITY:** 4
PROJECT LEADER: Hélène Couture **Tel:** 613-957-1742 **Fax:** 613-952-6400	**START DATE:** April 1994
PROJECT TEAM: Bureau of Microbial Hazards, AAFC	**PRE-PUBLICATION:** November 1996
RECOMMENDATIONS: 5.3, 5.4 (5-5)	**REGULATIONS:** B.08.002.2, B.08.030

OBJECTIVE	To amend B.08.002.2 to permit the use of technologies which provide equivalent assurance of safety of milk and dairy products as is achieved by (heat) pasteurization.
BACKGROUND	Regulation B.08.002.2 restricts the sale of dairy products to those that are pasteurized with exemptions for cheese and other food which will be further processed by pasteurization. Pasteurization is defined as a heat treatment for sufficient time to attain a specific tolerance for alkaline phosphatase activity according to the Official Method. The National Dairy Council has requested that references to pasteurization in the Regulations be amended to include "alternative processes which provide the same degree of safety" as pasteurization. This would remove impediments to the development and use of other suitable technologies.
APPROACH	Scientific literature will be reviewed and analyzed to quantify the effect of pasteurization on the microbiological end-product characteristics. In consultation with stakeholders, acceptable end-product safety will be defined. The amended regulation will describe a performance standard rather than a specific process.
CONSULTATION	National Dairy Council and dairy industry representatives, AAFC, provincial officials, members of academia, International Dairy Federation, consumer groups
IMPACT	This regulatory amendment will permit innovation and flexibility in the dairy industry. Inspection methods and testing to ensure safety of dairy products will change significantly.
DEPENDENCY	Independent

PROJECT: Dairy Microbiological Standards	**COMPLEXITY:** 3
PROJECT LEADER: Hélène Couture **Tel:** 613-957-1742 **Fax:** 613-952-6400	**START DATE:** April 1994
PROJECT TEAM: Bureau of Microbial Hazards, AAFC	**PRE-PUBLICATION:** March 1997
RECOMMENDATIONS: 5.5 (5-5)	**REGULATIONS:** B.08.016(e), B.08.018(f), B.08.026(g), B.08.062(d), B.08.072(d), B.08.048, B.08.054

OBJECTIVE	To amend the above regulations so that they apply to standardized and non-standardized dairy products and to provide for uniform microbiological criteria dependant on product type.
BACKGROUND	There are no microbiological criteria established for non-standardized products. The microbiological standards for product types such as fermented and non-fermented dairy products, including all types of cheese, are not uniform. For consumer protection, the same microbiological standards should apply to similar dairy product types since the risk related to these products should be the same.
APPROACH	Amend the regulations after a review and evaluation of the microbiological criteria that have been established or recommended by national or international organizations such as the International Dairy Federation (IDF), the provinces and AAFC. The term "fermentation" will need to be defined in order to determine the appropriate categorization of dairy products. Other criteria may have to be established for fermented products that are further processed.
CONSULTATION	Internally within HPB, AAFC, provincial governments, Quality Standards Committee of IDF, dairy industry manufacturers and national and provincial dairy industry associations, consumer groups
IMPACT	The impact on industry will be minimal. Public health would be maintained or improved.
DEPENDENCY	Independent

PROJECT: Smoked Fish	**COMPLEXITY:** 3
PROJECT LEADER: Karen Dodds **Tel:** 613-957-0884 **Fax:** 613-952-6400	**START DATE:** June 1994
PROJECT TEAM: Bureau of Microbial Hazards, DFO	**PRE-PUBLICATION:** November 1995
RECOMMENDATION: 5.7 (5-50)	**REGULATIONS**: B.21.025

OBJECTIVE	To amend section B.21.025 of the Regulations to outline the level of safety required in the final smoked fish and smoked fish product, rather than the specific conditions to achieve that safety.
BACKGROUND	B.21.025 was promulgated in response to several incidents of botulism food poisoning associated with vacuum packaged smoked fish. The regulation prescribes manufacturing processes and/or storage conditions that are intended to ensure the destruction of *C. botulinum* spores or preformed toxin, and/or that the spores do not germinate and grow during storage. Comments received from the smoked fish industry indicate that product processed to meet the prescribed safety factors has reduced quality and consumer acceptance.
APPROACH	The focus of the regulation should ensure the control of *C. botulinum* in the product as a performance standard rather than a prescription of how the control is to be achieved. This will permit the use of recent advances in food technology and processing to achieve the required level of safety. The industry must be aware of the importance of the different factors in the control of *C. botulinum* and must be able to meet any conditions described in amended regulations.
CONSULTATION	DFO, stakeholders in the smoked fish industry, provincial governments and consumer groups
IMPACT	Industry would be provided with greater flexibility in processing, packaging and storage temperature; consumer protection would be maintained.
DEPENDENCY	Independent

PROJECT: Salmonella in Frog's Legs	**COMPLEXITY:** 5
PROJECT LEADER: Hélène Couture **Tel:** 613-957-1742 **Fax:** 613-952-6400	**START DATE:** April 1994
PROJECT TEAM: Bureau of Microbial Hazards, DFO, AAFC	**PRE-PUBLICATION:** August 1997
RECOMMENDATIONS: 5.11 (5-40)	**REGULATIONS:** B.21.031

OBJECTIVE	To delete B.21.031 in conjunction with a consumer education campaign on the potential presence of pathogens in raw foods.
BACKGROUND	The original intent of the regulation requiring the absence of *Salmonella* from frog legs was to prevent the importation of exotic serotypes of *Salmonella* into Canada. This rationale should be re-examined in view of increasing global trade in food products. Further, these foods are not eaten raw, and any contaminating *Salmonella* would be destroyed during cooking.
APPROACH	International standards including production and manufacturing codes of practice to reduce/prevent contamination should be assessed. Consumer education such as the use of advisory material outlining safe handling and cooking instructions would be considered the preferred alternative in dealing with a product in which the presence of a particular microorganism is part of the ecology of the product.
CONSULTATION	Consultation with other federal food departments, the provinces, importers, industry, consumer groups as well as at the international level with source countries and other importing countries.
IMPACT	Cost for importers should be reduced. If the raw product is cooked properly, there should be no impact on consumers.
DEPENDENCY	Independent

APPENDICES

APPENDIX I

REGULATORY REVIEW - FOODS

SCOPE OF REGULATORY REVIEW

	Number of Recommendations	
LEAD AGENCY	REGULATORY AMENDMENTS	POLICY DEVELOPMENT
HEALTH CANADA		
Chemical Safety	9	6
Microbial Hazards	5	4
Nutrition	14	3
Regulatory Affairs	15	4
Veterinary Drugs	2	2
Branch Level	0	4
AGRICULTURE AND AGRI-FOOD CANADA		
Labelling	33	2
TOTALS	78	25

APPENDIX II

REGULATORY REVIEW - FOODS

EXTENT OF REGULATORY AMENDMENTS

Division of the *Food and Drug Regulations*		Number of Recommendations
1	General	21
2	Alcoholic Beverages	3
6	Food Colours	1
8	Dairy Products	9
9	Fats & Oils	1
11	Fruits/ Vegetables	3
12	Prepackaged Water & Ice	5
13	Grain & Bakery Products	3
14	Meat Products	8
15	Adulterants	4
16	Food Additives	9
17	Salt	2
19	Vinegar	2
21	Marine Products	3
22	Poultry Products	1
23	Packaging Materials	3
24	Foods for Special Dietary Use	4
25	Infant Foods	3
27	Low Acid Foods in Hermetically Sealed Containers	2
Part D	Nutrient Addition	4
TOTALS	21 Divisions	91

APPENDIX III

INVENTORY OF THE FOOD REGULATIONS REVIEWED DURING THE 1993 REGULATORY REVIEW

Section No.	*Regulation - Recommendation*	*Rec.*[1]	*Page*	*Contact*[2]	*Issue(s)*[3]	*Group*[4]
PART A OF THE FOOD AND DRUG REGULATIONS - ADMINISTRATION						
A.01.016	**Legibility Test** - examine feasibility of developing legibility test regarding prominence and ability to discern mandatory labelling information	3.1	3-9	A	L	6
PART B OF THE FOOD AND DRUG REGULATIONS - FOOD						
DIVISION 1 - GENERAL						
B.01	**Processing Aid** - define term and reference Codex Alimentarius in Regulations - define to distinguish from food additive; consider harmonization with US and Codex Alimentarius -provide for labelling exemption **Enzymes With Little Human Exposure** - de-list & develop alternative control (see also Div. 16)	4.7 3.13 4.6	4-10 3-10	C	C/L/M	6
B.01	**Food Additive Identification** - use common name/ class/ functional name or numerical identification system such as Codex Alimentarius - examination of requirements and alternatives (see also Div. 16)	3.12	3-10	C/A	C/L	6
B.01	**Date Marking:** 1) for products with modified atmosphere packaging 2) for low-acid foods in hermetically sealed containers 3) industry code for refrigerated food 4) foods with durable life date of more than 90 days - voluntary - amend/ develop new regulations (see also B.01.007)	3.15 3.16 5.16	3-14	M/A	M/L	6, 7
B.01	**Qualifiers for Common Names (General)** - harmonize with other federal departments and/or U.S.	3.18	3-16	A	L/N	6
B.01	**"Non-consumer package"** - define term; allow for exemptions from or providing flexibility in listing ingredients	3.4	3-10	A	L	6
B.01	**Ingredients Causing Allergic or Adverse Food Reactions** - develop list of ingredients causing anaphylaxis or severe allergic or adverse food reactions for ingredient labelling	3.9	3-10	A/C	L/C	6
B.01	**Nutrient Content Claims (Div. 24)** (e.g., "sugar-free", "low sodium") - transfer to Div. 1	4.12	4-2 3-16	N	N/L	4
B.01.003	**Requirement for Labelling on Bulk Food/ One Bite Confections** (requirement for label) - amend with respect to providing ingredient information for bulk food/ one bite confections (see also B.01.008)	3.5	3-10	A	L	6
B.01.003	**Mandatory Labelling of Non-Prepackaged Items** e.g., retail cooked meat, horsemeat, food additives, irradiated flour - amend after review of need for and manner of labelling	3.6	3-10	A	L	6
B.01.005	**Placement of Mandatory Information on Bottom of Container** (prohibition) - revoke	3.2	3-4	A	L	5
B.01.006	**Location of Common Name on label** - retain	3.19	3-1	A	L	1

Section No.	Regulation - Recommendation	Rec.[1]	Page	Contact[2]	Issue(s)[3]	Group[4]
B.01.006(1)	**Common Name** - amend to require that all words in common name be of equal prominence	3.20	3-16	A	L	6
B.01.007 (3)(c)(d)	**Doughnuts and Commissary Products Durable Life Date** - revoke exemption (see Date Marking project)	3.14	3-14	A	L	5
B.01.008	**Requirement for Labelling on Bulk Food/ One Bite Confections** (exemption of ingredient labelling) - amend with respect to providing ingredient information (also see B.01.003)	3.5	3-10	A	L	6
B.01.008(1)(a)	**Grouping of Mandatory Information with Ingredients** - revoke	3.3	3-4	A	L	5
B.01.008(1)(b) (3)(4)(5)(6)	**Manner of ingredient declaration** - retain (see B.01.011)	3.7	3-1	A	L	1
B.01.008(2) (7) - (10)	**Exemptions from Ingredient Labelling** - amend after review of validity, especially for foods packed at retail	3.8	3-10	A	L	6
B.01.009	**Component Exemptions** - re-examine for validity and consistency/ amend to require declaration of "priority allergens"	3.10	3-10	A	L/C	6
B.01.010	**Class Names, Source Names, Common Names** - amend after examination of ingredients causing allergic or adverse food reactions and to facilitate understanding	3.11	3-10	A/C	L/C	6
B.01.011	**Manner of ingredient declaration** - retain (see B.01.008	3.7	3-1	A	L	1
B.01.044	**Food additive limits and standards defined** - retain	4.9	4-1	C	C	1
B.01.045	**Food Colours** - eliminate certification and standards - reference F.C.C. and JECFA Compendium (see also Div. 6)	4.4	4-7	C	C	5
B.01.045	**Food additive limits and standards defined** - retain	4.9	4-1	C	C	1
B.01.046 B.01.047	**Contaminants** - review (see also Div. 15, Table 1)	2.6	2-7	C	C	6
B.01.049	**"Kosher"** - reexamine with a view to replacing with guidelines in Guide for Food Manufacturers and Advertisers, dealing with other optional claims	3.28	3-3	A	L	4
B.01.053	**Instant Breakfast** - revoke	4.23	4-3	N	N	5
B.01.056 (proposed)	**Interim Marketing Authorization (IMA)** - Develop submission guidelines - establish criteria for food additives, nutrients (1.7), agricultural chemicals (2.4), modify as bridging mechanism for existing food additives (4.3)	1.7 2.4 4.3	1-7	R	R	6
B.01.071	**Declare % of Predominant Nut in Mixed Nuts** - retain	3.21	3-1	A	L	1
B.01.072	**Smoked Foods** - amend for consistency (see also Div. 8)	3.27	3-20	A	L/C	6
B.01.080(2)	**"Previously Frozen"** - extend requirements to all products frozen and thawed prior to sale	3.17	3-14	A	L/M	6
B.01.100 (4)(a)(b)	**"Contains No Meat"** (declared on simulated meat and poultry) - revoke	3.23	3-4	A	L	5
DIVISION 2 - ALCOHOLIC BEVERAGES						
B.02.003	**Declare Alcohol Content on beverage PDP** - retain	3.21	3-1	A	L	1
B.02.021(b)	**Highland Whisky** - label/advertise with 51% Scottish malt whisky as distilled in Scotland - retain	3.25	3-1	A	L	1

Section No.	Regulation - Recommendation	Rec.[1]	Page	Contact[2]	Issue(s)[3]	Group[4]
B.02.022(1)	**Label/advertise Bourbon whisky** - retain	3.25	3-1	A	L	1
B.02.023 (old B.02.012)	**Aging of whisky in wood** - retain	3.25	3-1	A	L	1
B.02.032(old)	**Claim for the age of rum** - retain	3.25	3-3	A	L	1
B.02.033	**Composition of imported rum** - retain	3.25	3-2	A	L	1
B.02.034	**Rum from Commonwealth Caribbean Countries** - revoke after consultation with Dept's. of Revenue Canada and External Affairs	3.26	3-5	A	L	5
B.02.040(d) (old .02.040 (a)(b)	**Declare Holland's gin as distilled** - retain	3.25	3-2	A	L	1
B.02.040(e) (old B.02040(c))	**"Blended" Declaration on Holland's Gin PDP** - retain	3.21	3-2	A	L	1
B.02.043	**Age declaration for gin** - retain	3.25	3-2	A	L	1
B.02.059 (old B.02.057)	**Labelling of blended brandy as imported** - retain	3.25	3-2	A	L	1
B.02.060 (old B.02.053)	**Country of Origin - Imported Brandy** (declaration) - re-examine for relevancy, clarity, consistency	3.24	3-19	A	L	6
B.02.061 (old B.02.052)	**Declaration of age of brandy** - retain	3.25	3-2	A	L	1
B.02.108	**Country of Origin - All wine** (declaration) - re-examine for relevancy, clarity, consistency	3.24	3-19	A	L	6
DIVISION 4 - CACAO PRODUCTS						
B.04.010	**Salmonella in chocolate** - retain	5.1	5-1	M	M	1
B.04.011	**Salmonella in cocoa** - retain	5.1	5-1	M	M	1
DIVISION 6 - FOOD COLOURS						
B.064-18	**Food Colours** - eliminate certification and standards - use F.C.C. and JECFA Compendium (see also B.01.045)	4.4	4-7	C	C	5
DIVISION 8 - DAIRY PRODUCTS						
B.08	**Smoked Cheese** - re-examine (see B.01.072)	3.27	3-20	A	L	6
B.08	**Vitamin A Addition to Reduced Fat Dairy Products** - new regulations under Div. 8 and D.03.002	4.25	4-19	N	N	6
B.08.002.2	**Pasteurization** - amend with consultation on definitions & verification of technologies	5.3 5.4	5-7	M	M	6
B.08.003 B.08.004 B.08.005 B.08.007	**Fortification** - revise for consistency of units of measure and difference between maximums and overages	4.21	4-4	N	N	6
B.08.007	**Sterilized Milk** - revoke	5.12	5-2	M	M	5
B.08.009 B.08.010 B.08.013 B.08.014	**Fortification** - revise for consistency of units of measure and difference between maximums and overages	4.21	4-4	N	N	6
B.08.014A	**Salmonella in milk powder** - retain	5.1	5-1	M	M	1

Section No.	*Regulation - Recommendation*	*Rec.*[1]	*Page*	*Contact*[2]	*Issue(s)*[3]	*Group*[4]
B.08.016	**Fortification** - revise for consistency of units of measure and difference between maximums and overages	4.21	4-4	N	N	6
B.08.016(e)	**Dairy Microbiological Standards** - amend for uniform application to standardized and unstandardized products	5.5	5-8	M	M	6
B.08.017 B.08.018	**Fortification** - revise for consistency of units of measure and difference between maximums and overages	4.21	4-4	N	N	6
B.08.018(f)	**Dairy Microbiological Standards** - amend for uniform application to standardized and unstandardized products	5.5	5-8	M	M	6
B.08.019 B.08.020 B.08.023	**Fortification** - revise for consistency of units of measure and difference between maximums and overages	4.21	4-4	N	N	6
B.08.024 B.08.025	**Bacteria in Raw Milk for Manufacture** - revoke & transfer to Agriculture Canada or Provinces	5.9	5-2	M	M/R	5
B.08.026	**Fortification** - revise for consistency of units of measure and difference between maximums and overages	4.21	4-4	N	N	6
B.08.026(g)	**Dairy Microbiological Standards** - amend for uniform application to standardized and unstandardized products	5.5	5-7	M	M	6
B.08.029	**Fortification** - revise for consistency of units of measure and difference between maximums and overages	4.21	4-4	N	N	6
B.08.030	**Cheese from Heat-Treated Milk** (cheese from unpasteurized source) - amend to require heat treatment of milk or cheese; consider provision for the use of other technologies	5.4	5-2	M	M	4
B.08.031(b)	**State source of milk for cheese** - retain	3.21	3-2	A	L	1
B.08.032	**Moisture in Cheese** (declaration) - revoke	3.23	3-4	A	L	5
B.08.032(1)	**Milk Fat Declaration** - amend to require mandatory declaration in grams fat/ serving instead of % milk fat.	3.22	3-2	N	N/L	6
B.08.042 - B.08.047	**Cheese from Heat-Treated Milk** (cheese from unpasteurized source) - amend to require heat treatment of milk or cheese; consider provision for the use of other technologies	5.4	5-2	M	M	4
B.08.048 B.08.054 B.08.062(d) B.08.072(d)	**Dairy Microbiological Standards** - amend for uniform application to standardized and unstandardized products	5.5	5-7	M	M	6
B.08.074(1) B.08.076(1)	**Milk Fat Declaration** - amend to require mandatory declaration in grams fat/ serving instead of % milk fat.	3.22	3-2	N	N/L	6
DIVISION 9 - FATS AND OILS						
B.09.012	**Mono- & Diglycerides** - revoke standards and use reference to F.C.C. as per B.01.045	4.8	4-3	C	C	5
B.09.016 B.09.017	**Fortification** - revise for consistency of units of measure and difference between maximums and overages	4.21	4-4	N	N	6
DIVISION 11 - FRUITS, VEGETABLES, THEIR PRODUCTS AND SUBSTITUTES						
B.11.015	**Tomato Trimmings in Catsup** (declaration) - revoke	3.23	3-4	A	L	5
B.11.016 B.11.017	**Mould in Tomato Products** - revoke (rejected).	5.13	5-1	M	M	2

Section No.	Regulation - Recommendation	Rec.[1]	Page	Contact[2]	Issue(s)[3]	Group[4]
B.11.105	**Antioxidant Addition to Frozen Fruit** (indication of ascorbic acid/ erythorbic acid addition) - revoke	3.23	3-4	A	L	5
B.11.123 B.11.124 B.11.128A B.11.130 B.11.132 B.11.134	**Fortification** - revise for consistency of units of measure and difference between maximums and overages	4.21	4-4	N	N	6
B.11.204	**Addition of Pectin to Jam** (declaration on PDP) - re-examine for relevancy, clarity, consistency	3.24	3-18	A	L	5
DIVISION 12 - PREPACKAGED WATER AND ICE						
B.12	**Location of Mandatory Information on Water & Ice** - consider alternative location of certain PDP mandatory information; allow anywhere on label.	3.31	3-4	A	L	4
B.12	**Chemical Contaminants in Water & Ice** - develop new regulations.	4.29	4-2	C	C	4
B.12.001	**Fortification** - revise for consistency of units of measure and difference between maximums and overages	4.21	4-4	N	N	6
B.12.001(b)	**Microbiological Standards for Water & Ice** - amend to achieve uniformity and include other microorganisms.	5.6	5-2	M	M	4
B.12.002	**Ozone in Water & Ice** - consider revocation of requirement for declaration when used as a processing aid	3.29	3-4 3-10	C	C/L	4
B.12.002(c)	**Fluoride Declaration on Water & Ice** (fluoride declaration) - consider need when fluoride is not added	3.30	3-4	C	C/L	4
B.12.004	**Fortification** - revise for consistency of units of measure and difference between maximums and overages	4.21	4-4	N	N	6
B.12.004(a) (b) B.12.005 1(a) 2(a)	**Microbiological Standards for Water & Ice** - amend to achieve uniformity and include other microorganisms	5.6	5-2	M	M	4
DIVISION 13 - GRAIN AND BAKERY PRODUCTS						
B.13	**Cereal & Grain Enrichment** - new regulation	4.25	4-15	N	N	6
B.13.001 (d)(e)(xv)(f)	**Fortification** - revise for consistency of units of measure and difference between maximums and overages	4.21	4-4	N	N	6
B.13.001(g)	**Irradiated Flour** (declaration that gamma irradiated flour is "treated" with ionizing radiation) - re-examine for relevancy, clarity, consistency (revoke?)	3.24	3-4	A	L/C	5
B.13.005(e)	**Irradiated Whole Wheat Flour** (declaration that gamma irradiated whole wheat flour is "treated" with ionizing radiation) - re-examine for relevancy, clarity, consistency	3.24	3-4	A	L/C	5
B.13.010.1(2)	**Fortification** - revise for consistency of units of measure and difference between maximums and overages	4.21	4-4	N	N	6
B.13.028	**Brown Bread Labelling** - revoke	3.23	3-4	A	L	5
B.13.060	**Fortification** - revise for consistency of units of measure and difference between maximums and overages	4.21	4-4	N	N	6
DIVISION 14 - MEAT, ITS PREPARATIONS AND PRODUCTS						
B.14	**Meat and Poultry Regulations** - combine Div. 14 & 22	—[5]	4-4	R	R	6

Section No.	*Regulation - Recommendation*	*Rec.*[1]	*Page*	*Contact*[2]	*Issue(s)*[3]	*Group*[4]
B.14.009(g)	**Enzymes in Pumping Pickle** (declare use on PDP) - re-examine for relevancy, clarity, consistency	3.24	3-18	A	L	5
B.14.013 B.14.014	**Meat in Hermetically Sealed Container** - revoke	5.14	5-2	M	M	5
B.14.016	**Horsemeat** (declaration) - revoke	3.23	3-5	A	L	5
B.14.018	**Bulk Beef and Veal Advertisements** - amend to include declaration of grade and class designation	3.22	3-6	A	L	6
B.14.019 (1)(a)(b)	**Declaration of selling price and additional charges on meat carcass** - retain	3.25	3-2	A	L	1
B.14.031(f) (g)(gg)	**Flavouring of Preserved Meat** (declaration on PDP) - revoke	3.23	3-5	A	L	5
B.14.032(d)(xii) (xiv)(A)(B)	**Flavouring of Sausage** (declaration on PDP) - revoke	3.23	3-5	A	L	5
B.14.061	**Edible Bone Meal & Flour** (microbiological standard) - revoke	5.15	5-2	M	M	5
B.14.062	**Gelatin** - revoke standards and use B.01.045, reference to the standard in the Food Chemicals Codex (F.C.C.).	4.8	4-1	C	C	2
B.14.062	**Gelatin** (microbiological standard) - revoke	5.15	5-2	M	M	5
B.14.072	**Cooked Meat Storage** (BBQ, roasted, broiled sold at retail) - revoke and transfer to Provinces	5.10	5-3	M	M	5
DIVISION 15 - ADULTERATION OF FOOD						
B.15	**Vet. Drugs & Agricultural chemicals** (regulations/ tables) - retain	2.1	2-1	V	V	1
B.15	**Veterinary Drugs Regulations** - consolidate	2.2	2-3	V	V	6
B.15	**Veterinary Drugs Regulations** - expand	2.2	2-6	V	V	6
B.15	**Establish Separate Veterinary Drug Regulations**	----[6]	2-2	V	V	2
B.15	**Food Chemical Contaminants** - continue with current control mechanisms	2.5	2-1	C	C	1
B.15	**Contaminants** - (Table 1 to Div. 15) - review (see also B.01.046, B.01.047)	2.6	2-7	C	C	6
B.15.002	**Agricultural chemicals** - (0.1 ppm MRL) - review/ consult	2.3	2-11	C	C	6
DIVISION 16 - FOOD ADDITIVES						
B.16	**Processing Aid** - define term and reference Codex Alimentarius in Regulations - define to distinguish from food additive; consider harmonization with US and Codex Alimentarius -provide for labelling exemption **Enzymes With Little Human Exposure** - de-list & develop alternative control (see also Div. 1)	4.7 3.13 4.6	4-10 3-10	C	C/L/M	6

Section No.	*Regulation - Recommendation*	*Rec.*[1]	*Page*	*Contact*[2]	*Issue(s)*[3]	*Group*[4]
B.16	**Food Additive Tables - Consolidation** - consolidate food additives into one table listing by alphabetical order, areas of use by food class, with maximum level of use specified for each class **Food Additive Identification** - use common name/ class/ functional name or numerical identification system such as Codex Alimentarius - examination of requirements and alternatives **Food Additive Tables - GMP Level Food Additives (Undefined ADI)** - establish a positive list without regard to specified areas or level of use	1.9 4.2 3.12 4.1	4-6	C	C	6
B.16	**Flavour Enhancers** - define term and reference Codex Alimentarius in Regulations	4.7	4-8	C	C	6
B.16.001	**Quantitative Statement on Food Additives** (quantitative statement of amount/ directions for use grouped with ingredients of food additive products) - re-examine for relevancy, clarity, consistency	3.24	3-3	C	C/L	1
B.16.004	**Prohibition of Combinations of Class II Preservatives** - revoke	4.5	4-3	C	C	5
DIVISION 17 - SALT						
B.17.001(2)	**Free-running Salt** (declaration) - revoke	3.23	3-5	A	L	5
B.17.003	**Iodide in Salt** (declaration on PDP) - re-examine for relevancy, clarity, consistency	3.24	3-3	N	N/L	3
B.17.003	**Fortification** - revise for consistency of units of measure and difference between maximums and overages	4.21	4-4	N	N	6
DIVISION 19 - VINEGAR						
B.19.002	**Vinegar Acetic Acid** (declare % acetic acid on vinegar PDP) - re-examine for relevancy, clarity, consistency	3.24	3-18	A	L	6
B.19.008	**Blended Vinegar** (labelling) - reassess/consider developing guidelines to be included in Guide for Food Manufacturers and Advertisers dealing with other optional claims	3.28	3-20	A	L	6
B.19.009	**Vinegar Acetic Acid** (declare "For manufacturing use only" on vinegar with acetic content over maximum) - re-examine for relevancy, clarity, consistency	3.24	3-18	A	L	6
DIVISION 21 - MARINE AND FRESH WATER ANIMAL PRODUCTS						
B.21.006(g)	**Flavouring Added to Fish** (declaration) - revoke (incorrectly listed in Vol. 1 as B.22.006(g))	3.23	3-5	A	L	5
B.21.025	**Smoked Fish** (refrigerated smoked fish in sealed containers to exclude air) - amend to include new information re: <u>C. botulinum</u>	5.7	5-9	M	M	6
B.21.027	**Fish Protein** (microbiological standard) - revoke	5.15	5-3	M	M	5
B.21.031	**Frog's Legs** - phased deregulation	5.11	5-10	M	M	5
DIVISION 22 - POULTRY, POULTRY MEAT, THEIR PREPARATIONS AND PRODUCTS						
B.22	**Meat and Poultry Regulations** - combine Div. 14 & 22	—[5]	4-4	R	R	6
B.22.026	**Cooked Poultry Storage** (BBQ, roasted, broiled sold at retail) - revoke and transfer to Provinces	5.10	5-3	M	M	5
B.22.033	Salmonella in egg products - retain	5.1	5-1	M	M	1

Section No.	*Regulation - Recommendation*	*Rec.*[1]	*Page*	*Contact*[2]	*Issue(s)*[3]	*Group*[4]
DIVISION 23 - FOOD PACKAGING MATERIALS						
B.23	**Food Packaging Materials** (voluntary pre-market review) - retain	2.7	2-1	C	C	1
B.23	**Food Packaging Materials - Official Methods FO-40 & FO-41** - update methods	2.7	2-3	C	C	6
B.23	**Food Packaging Materials - Evidence of Safety** - new regulations	2.8	2-1	C	C	2
B.23	**Food Packaging Materials - Recycled Materials in Direct Food Contact** - consider development of regulations or guidelines	2.8	2-4	C	C	6
DIVISION 24 - FOODS FOR SPECIAL DIETARY USE						
B.24	**Nutrient Content Claims (Div. 24)** (e.g., "sugar-free", "low-sodium") - transfer to Div. 1	4.12	4-2 3-16	N	N/L	4
B.24	**Nutritionally Balanced Food Supplements** - develop regulations with increased flexibility	4.13	4-11	N	N	6
B.24	**Formulated Liquid Diets (Medical Foods)** - restrict formulated liquid diet products to Codex Alimentarius standard for "medical foods"; permit greater flexibility in formulation	4.14	4-12	N	N	6
B.24	**Experimental Formulated Liquid Diets** - consider use of B.01.054 - Temporary Marketing Authorization (TMA)	4.15	4-12	N	N	6
B.24	**Foods for use in Weight Reduction Diets/ Maintenance of Healthy Weights** - revise as per I.L. 793 (April '91)	4.16	4-2	N	N	4
DIVISION 25 - INFANT FOODS, INFANT FORMULA						
B.25	**"Infant Formula for Special Dietary Needs"** - amend to provide for formulas for infants with special dietary needs	4.17	4-13	N	N	6
B.25	**Experimental Infant Formula** - consider use of B.01.054 - Temporary Marketing Authorization (TMA)	4.18	4-14	N	N	6
B.25.046 B.25.048	**Infant Formula** - amend to include importers	4.19	4-4	N	N	6
DIVISION 26 - FOOD IRRADIATION						
B.26	**Food Irradiation** (regulations) - retain	2.9	2-1	C	C	1
DIVISION 27 - LOW-ACID FOODS PACKAGED IN HERMETICALLY SEALED CONTAINERS						
B.27	**Low Acid Food in Hermetically Sealed Containers** - consider establishing a date marking system (see Div. 1 Date Markings)	3.16	3-14	M/A	M/L	6
B.27	**Low Acid Food in Hermetically Sealed Containers** - amend to tighten control over imports	5.8	5-4	M/R	F/M	6
PART D OF THE FOOD AND DRUG REGULATIONS - VITAMINS, MINERALS AND AMINO ACIDS						
DIVISION 1 - VITAMINS IN FOODS / DIVISION 2 - MINERAL NUTRIENTS IN FOODS						
D.01.009 D.01.010 D.01.011 D.02.009 D.02.010 D.02.011	**Nutrient Addition - General Provisions** (Part D) - develop commodity specific regulations for nutrient addition to infant cereal, instant breakfast, flavoured beverage mixes and add to the appropriate Division of Part B of the Regulations (delete after new regulations developed)	4.26	4-16	N	N	6

Section No.	*Regulation - Recommendation*	*Rec.*[1]	*Page*	*Contact*[2]	*Issue(s)*[3]	*Group*[4]
DIVISION 3 - ADDITION OF VITAMINS, MINERAL NUTRIENTS OR AMINO ACIDS TO FOODS						
D.03	**Nutrient Restoration** (Part D nutrients lost during processing, etc.) - develop new regulation to allow addition of nutrients without pre-market notification and amendment of the Regulations (see also B.08 (4.25) and B.13 (4.25))	4.24	4-19	N	N	6
D.03.002	**Fortification** (listing vitamins which may be added to specific categories of food) - retain	4.20	4-1	N	N	1
D.03.002	**Nutrient Addition** - modify Table by adding references to specific regulations	4.22	4-4	N	N	6
D.03.002	**Vitamin A Addition to Reduced Fat Dairy Products** - new regulations under Div. 8 and D.03.002	4.25	4-19	N	N	6
D.03.003	**Exemption for Foods for Special Dietary Use** - retain	4.23	4-1	N	N	1
Part D	**Schedule K - Basis of Protein Claims** - retain	4.27	4-1	N	N	1

NOTES TO TABLE OF REGULATIONS

[1] **REC.:** Numbers refer to recommendations listed in Chapter 5, Summary of Recommendations in **A Strategic Direction for Change: A review of the regulations under the Food and Drugs Act.** (Volume 1). HPB 1993.

[2] **CONTACT:**

HEALTH CANADA

C - Bureau of Chemical Safety, HPB
M - Bureau of Microbial Hazards, HPB
N - Nutrition Evaluation Division, HPB
P - Office of Policy and Scientific Affairs, HPB
R - Bureau of Food Regulatory, International and Interagency Affairs, HPB
V - Bureau of Veterinary Drugs, HPB

AGRICULTURE AND AGRI-FOOD CANADA

A - Agriculture and Agri-Food Canada (food labelling issues)

[3] **ISSUE(S):** The issues involved in any project correspond to and are described by using the abbreviations for the Lead Agencies. L for Labelling has been added.

[4] **GROUP:** Refers to the section of the Implementation plan where more information may be found regarding the status of the recommendation made:

1 - Regulations that are Recommended for Retention
2 - Recommendations that have been Rejected
3 - Recommendations that have been Reviewed and Action Completed
4 - Recommendations Already in the Regulatory Process or Part of a Larger Departmental Initiative
5 - Regulations Recommended for Revocation
6 - Recommendations for Regulatory Amendments
7 - Recommendations for Policy Development

[5] ---- Indicates a recommendation which was not listed, but discussed in Volume 1 or suggested internally after Phase I.

[6] ---- Recommended by the Canadian Animal Health Institute.

APPENDIX IV

INVENTORY OF RECOMMENDED POLICY DEVELOPMENT INITIATIVES

Project Name - Recommendation	*Rec.*[1]	*Page*	*Contact*[2]	*Group*[3]
Standards - **Improve coordination of legislated standards**/ use of reference to international, National Standards System (NSS), or other standards - **Transfer compendium of standards** of identity & composition to Standards Council of Canada	1.1 1.8 4.11	1-9	R	7
Inspection Policy - develop/ communicate policy which would reduce inspections for companies meeting quality management standards	1.2	1-1	R	7
Revisions to the Food and Drugs Act - Definitions	1.3	1-2		
Revisions to the Food and Drugs Act - Miscellaneous Concerns	1.3	1-2		
Revisions to the Food and Drugs Act - Delegation of authority, (Vol. 1, p.55) - review and consolidate delegations of regulatory powers so that decisions can be made at the appropriate levels of responsibility	—	1-7	P	7
Revenue Generation (Fees) - registration/ licensing firms, product/ label evaluation/ approval, issuance of export certificates, publication costs - examine feasibility	1.4	1-3	P	4
Food Import Control - develop coherent compliance policy for imports	1.5	1-3	R	7
Food Compliance (Enforcement) Policy - develop and communicate	1.6	1-4	R	7
Fast Track Evaluation (FTE) - establish criteria for submission guidelines	1.7	1-11	C	7
Communication/ Consultation - develop plan re: regulatory policy, regulatory initiatives, status	—[4] 7.1a,b,c	I-5 I-6	R	7
Enforcement of Irradiated Food (Div. 26) - Improve enforcement capability (especially for imports)	2.9	2-4	C	7
Food Irradiation Education - consider development of consumer education program	2.9	2-4	C	7
Principles of Labelling Implementation - **Presentation of Labelling Regulations**- re-draft for clarity and ease of use - **Consultation on Labelling Issues** - continue sector by sector approach; focus groups, meetings, etc.	3.32 3.33	3-6	A	7
Strategic Plan for Implementation of Improved Labelling System - develop a strategic plan for immediate and short term action with implementation dates which consolidate all labelling changes - develop plan for periodic assessment or automatic termination	3.34	3-6	A/R	7
Labelling Research - consider conducting research re: consumers needs; especially in the area of ingredient labelling	3.35	3-7	A	7
Subsection 4(d) of Food and Drugs Act - use as Authority for Food Additive Tables - (similar to Div. 15) - study option	4.10	4-2	R	2
Duplicate Standards - identify and revoke regulations which are duplicated in the Agricultural Products Act, Meat Inspection Act, or Fish Inspection Act	4.11	4-9	R	6
Substitute Foods (general & dairy products) - Fed./Prov./Industry consultation required to develop new regulations	4.28	4-17 4-19	N	7
Regulation of Refrigerated Foods - monitor & develop industry code	5.16	5-3	M	7

Project Name - Recommendation	*Rec.*[1]	*Page*	*Contact*[2]	*Group*[3]
Microbiological Guidelines - review	5.17	5-3	M	7
Extraneous Material Guidelines (Sect. 4 & 7 of Act) - develop MOUs	5.18	5-4	M	7
Microorganism Specific "Official methods" - modify to be microorganism specific/ equivalent methods	5.19	5-4	M	7

NOTES TO TABLE ON POLICY DEVELOPMENT INITIATIVES

[1] **REC.:** Numbers refer to recommendations listed in Chapter 5, Summary of Recommendations in **A Strategic Direction for Change: A review of the regulations under the Food and Drugs Act.** (Volume 1). HPB 1993.

[2] **CONTACT:**

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AGRICULTURE AND AGRI-FOOD CANADA

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[4] ---- indicates a recommendation which was not listed, but discussed in Volume 1 or suggested internally after Phase I.

APPENDIX V

REGULATORY AMENDMENT PROCESS

FOOD AND DRUG REGULATIONS

Step	
1	Scientific Review
2	Preparation of Schedule of Amendment
3	Legal Review
4	Ministerial Review
5	Pre-Publication in *Canada Gazette Part I*
6	Comment Period
7	Revision of Schedule of Amendment
8	Legal Review
9	Ministerial Review
10	Publication in *Canada Gazette Part II*

APPENDIX VI

HPB BBS

** HIN User guide abstract **

(Health Information Network, HIN, BBS and HPB BBS are used interchangeably)

1. **Technical requirements:** PC, modem, terminal emulation software (VT100, VT102, VT220)

2. **Communication parameters:** auto-baud up to 19,200, N/8/1

3. **Initiating a BBS session**

- Dial: 1-613-952-9597
- Press semi-colon <;> after the "**connect**" message
- A menu will then be displayed, select the option that says: **Health Protection Branch BBS** (option 5).
- **Log on to the HINet server** as follows:
  SunOS Unix (hpb1.hwc.ca)
  login: **hpbnet** <enter> /* in lower case */
- **Sign on to the HINet**: This part includes a dialogue where you get the opportunity to register yourself on the BBS, state your terminal type, and enter your user name and password.

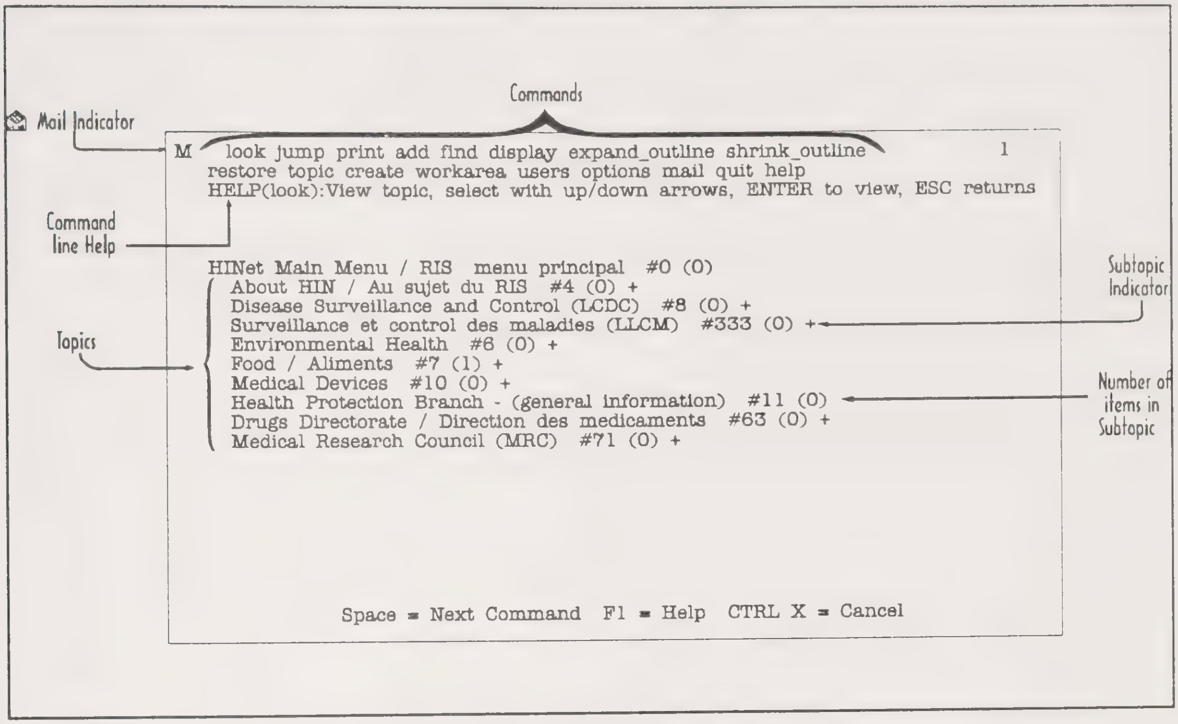
4. **BBS Topic and Menu Layout**

The main BBS screen for is displayed below. The layout is the same for virtually all BBS screens:

- commands appear in the top two or three rows of the screen
- BBS contents such as topics, subtopics, entries, mail etc. appear below the commands. The commands actually displayed are dependent upon the type of information currently displayed on the screen.

The BBS has several topic and sub-topic areas which contain documents that can be displayed or downloaded.

Use the Up/Down arrow key to select the topic areas or documents that you wish to access. Use the space bar to select a command, then press <enter> to execute it.



```
M   look jump print add find display expand_outline shrink_outline          1
    restore topic create workarea users options mail quit help
    HELP(look):View topic, select with up/down arrows, ENTER to view, ESC returns


    HINet Main Menu / RIS  menu principal  #0 (0)
      About HIN / Au sujet du RIS  #4 (0) +
      Disease Surveillance and Control (LCDC)  #8 (0) +
      Surveillance et control des maladies (LLCM)  #333 (0) +
      Environmental Health  #6 (0) +
      Food / Aliments  #7 (1) +
      Medical Devices  #10 (0) +
      Health Protection Branch - (general information)  #11 (0)
      Drugs Directorate / Direction des medicaments  #63 (0) +
      Medical Research Council (MRC)  #71 (0) +




                Space = Next Command  F1 = Help  CTRL X = Cancel
```

Sample Menu and Topic Indicators

5. Additional documentation

Once logged on, it is recommended that you download the Health Canada HIN (startup guide) and the "TEAMate User Guide" (optional) . These two entries are found under the "About Health Net" topic area.

6. How to download Documents

To download the "Startup guide" , proceed as follows:

1. Highlight "**About HIN / Au sujet du RIS**" , press <enter>
2. Highlight "**BBS guide downloads / Repertoire des guides...**", press <enter>
3. Highlight "**Health Canada HIN / BBS ...**", press <enter>
4. Press 'p' /* this is the print command (i.e. download) */
5. **To:** Press the first letter of the transfer protocol to use to download, press <tab>
6. **Select entry:** Press <tab>
7. **Format:** Press 'a' /* attachment */

Ex: Your screen should look like this (if Zmodem was selected):

```
To:  [terminal file auto xmodem ymodem zmodem kermit ftp workarea]
  Select entry:  [this all new mark one_marked two_marked]
      Format:  [print transaction attachment summary object]

 1236 tmadmin   MMB TEAMate user gui Sep 12 10:50:32 1994  t   a
 1235 tmadmin   Health Canada HIN/BB Sep 12 10:45:55 1994  t   a
```

8. Press <enter> to start the download
9. Depending on the selected transfer protocol, you may be have to issue "file receive" commands in your communication program.

7. Navigational Tips

7.1 To move down the document one page, if the <pg dn> does not work, try <ctl>+n.

7.2 To exit from a Word Perfect document, try <F7>, if that does not work, try the following sequence: <ctl>+[then [then <ctl>+c.

You should now have exited Wordperfect. If not, try again and add these steps. You may not see the prompts, but type "n" and "y" anyway.

At the "Save Document? (Y/N) Yes" prompt, type n.
At the "Exit WP (Y/N) No" prompt, type y.

8. Command summary

Look	Go to selected (highlighted) topic area
Jump	Go directly to a topic area
Print	Download selected document
Add	Upload a document
Find	Find documents according to the specified selection criteria
Display	Display selected (highlighted) document
Expand_outline	Display sub-topics
Shrink_outline	Return to previous topic
Users	Display information about BBS users
Quit	Terminate BBS session and leave system
Help	Display help on selected (highlighted) command

INTERNET ACCESS

Technical Requirements: PC, modem, terminal emulation software (VT100, VT102, VT220), Internet access

1. **HPB File Server Internet Address:** hpb1.hwc.ca or 142.4.1.2

2. **Telnet:** type: telnet hpb1.hwc.ca, login as hpbnet

3. **WWW:** type: http://hpb1.hwc.ca
   Follow the hypertext links to the Regulatory Review

4. **GOPHER:** type: gopher://hpb1.hwc.ca
   Follow the menu items to Regulatory Review

5. **INTERNET MAILING LIST:** The mailing list software used is **Majordomo** whose address is: **majordomo@hpb.hwc.ca**

a. To subscribe (i.e. put yourself on the mailing list) to the Regulatory Review UPDATE send this message to majordomo:
subscribe RRUpdate

b. To cancel your subscription to the Regulatory Review *UPDATE* send this message to majordomo: **unsubcribe RRUpdate**

c. To obtain some background information about the Regulatory Review send this message:
info RRUpdate

The UPDATE will be forwarded automatically by Majordomo on a periodic basis (to be determined).

APPENDIX VII

HPB REGULATORY REVIEW COMMUNICATIONS SURVEY

The **Regulatory Review** *UPDATE* will provide progress reports on individual projects and can be provided either electronically (DOS Text or Word Perfect formats) or in printed form. Your cooperation is requested, to establish mailing lists dependent on communications access and thus facilitate the access and distribution of the **Updates**. Please indicate below the communications methods available to you and describe your situation as appropriate.

Name: ____

Title/Organization: ____

Address:____

____

____

Telephone: ________________ Fax: ____________________

Internet Email address: ______________________________

Internet access available(i.e. WWW, Gopher): ☐

Bulletin Board Access (via computer modem): ☐

Please mail ____ copies of ***Volume 3***.

I do not currently have electronic access and would like to receive the ***UPDATE*** ☐

Please complete this questionnaire and mail, fax or send via Internet your response to:

Gary Trivett
Food Directorate
Room 200, HPB Bldg.
Tunney's Pasture
Ottawa, ON K1A 0L2
Tel: 613-957-1316
Fax: 613-941-3537
Internet: gtrivett@hpb.hwc.ca

APPENDIX VIII

GOVERNMENT LEAD AGENCIES

HEALTH CANADA

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Chemical Evaluation Division
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Tunney's Pasture
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Fax: 613-941-6636

Bureau of Food Regulatory, International
and Interagency Affairs
Room 200, HPB Building
Tunney's Pasture
Ottawa, Ontario K1A 0L2
Tel: 613-957-1828
Fax: 613-941-3537

Bureau of Veterinary Drugs
Room 2605-C, Main Statistics Canada Building
Tunney's Pasture
Ottawa, Ontario K1A 0L9
Tel: 613-957-3857
Fax: 613-957-3861

AGRICULTURE AND AGRI-FOOD CANADA

Food Division
Food Production and Inspection Branch
Agriculture and Agri-Food Canada
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Fax: 613-952-7387